

Baseline Assessment Form

(To be completed by Research Nurse prior to randomisation. Please complete text in BLOCK CAPITALS, tick the appropriate box or enter numbers into the boxes provided.)

Date of Admission: / (dd/mm/yy).

Date of Assessment: / (dd/mm/yy).

Centre Name: _____ Centre Number:

Recruiting Consultant: _____

Full Name of Patient: _____

Patient's Address: _____

_____ Telephone No.: _____

Patient's Full Post Code:

Patient's Date of Birth: /

Gender: MALE FEMALE

GP Name: _____

GP Address: _____

_____ Telephone No.: _____

Trial Leg: RIGHT LEFT

Risk Factors

Smoking: NEVER SMOKED
CURRENT No. of years smoked:
EX-SMOKER No. of cigarettes per day:
No. of years smoked:
Years since last cigarette:

Diabetes: NO INSULIN DEPENDENT NON-INSULIN DEPENDENT

Hypercholesterolaemia: NO YES - UNTREATED YES - TREATED

Hypertension: NO YES - UNTREATED YES - TREATED

Patient Mobility

Independent Cane/Walker Prosthesis Wheelchair Bed-bound

Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial

Baseline Assessment Form

Case Reference No: _____

Past Medical HistoryPrevious MI: NO YES Angina: NO YES - ON EXERCISE YES - AT REST TIA: NO YES Stroke: NO YES

Other: _____

Previous intervention to trial leg: NO YES If YES: PTA Stent Surgery Digital/Forefoot Amputation
Supra-inguinal Infra-inguinal Is the other leg symptomatic? NO YES If YES: Intermittent Claudication Severe Limb Ischaemia
Category: A B C D Previous intervention to other leg: NO YES If YES: PTA Stent Surgery
Amputation : Digits Forefoot Trans-tibial Trans femoral **Clinical Status**Patient's height (cm): Patient's weight (kg): Pulse: Brachial blood pressure: Right: / Left: /Ankle pressures in trial leg: (insert not found [NF] if no signal insonated)
for patients with compressible vessels record cuff pressure: for patients with incompressible ankle vessels record toe pressure or height (cm) above bed where Doppler signal lost (pole test)

	Cuff pressure	or	Height (cm) above bed
Dorsalis pedis	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Posterior tibial	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Perforating peroneal	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Toe pressure	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		

Ankle:brachial pressure index in trial leg =
(highest ankle pressure/highest brachial pressure)

Blood test results on admission

(* delete as necessary. Please enter ND if analysis is not done)

	<u>Test Result</u> (Please include units)	<u>Date of Tests</u>
Haemoglobin:	_____	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
White cell count:	_____	
Platelet count:	_____	
Creatinine:	_____	
Fasting/Random* glucose:	_____	
Fasting/Random* triglyceride:	_____	
Total cholesterol:	_____	
Other Tests (please specify):	_____	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
	_____	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>
	_____	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/>

PATIENT NUMBER

One-Month Clinical Follow-up Form

(To be completed by Research Nurse. Please complete text in BLOCK CAPITALS, tick the appropriate box or enter numbers into the boxes provided.)

Date of Assessment: (dd/mm/yy)

Recruiting Consultant: _____

Patient's Date of Birth: Gender: MALE FEMALE
(dd/mm/yy)

Trial Leg: LEFT RIGHT

Date of Primary Intervention: (dd/mm/yy)

Type of Primary Intervention: PTA SURGERY

Further Interventions: NONE PTA SURGERY AMPUTATION

Dates of Further Interventions:

Clinical status

Pulse:

Brachial blood pressure: Right: Left:

Ankle pressures in trial leg: (insert not found [NF] if no signal insonated)
for patients with compressible vessels record cuff pressure: for patients with incompressible ankle vessels record toe pressure or height (cm) above bed where Doppler signal lost (pole test)

	Cuff pressure	or	Height (cm) above bed
Dorsalis pedis	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Posterior tibial	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Perforating peroneal	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Toe pressure	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		

Ankle:brachial pressure index in trial leg = .
(highest ankle pressure/highest brachial pressure)

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
One-Month Clinical Follow-up Form**

Patient Mobility

Independent Cane/Walker Prosthesis Wheelchair Bed-bound

PATIENT NUMBER //

Pattern of tissue loss

Rest Pain:	ABSENT	<input type="checkbox"/>	IMPROVED	<input type="checkbox"/>	UNCHANGED	<input type="checkbox"/>
	WORSE	<input type="checkbox"/>	NA	<input type="checkbox"/>	AMPUTATION	<input type="checkbox"/>
Ulceration:	HEALED	<input type="checkbox"/>	IMPROVED	<input type="checkbox"/>	NO CHANGE	<input type="checkbox"/>
	WORSE	<input type="checkbox"/>	NA	<input type="checkbox"/>	AMPUTATION	<input type="checkbox"/>
Gangrene:	ABSENT	<input type="checkbox"/>	IMPROVED	<input type="checkbox"/>	NO CHANGE	<input type="checkbox"/>
	WORSE	<input type="checkbox"/>	NA	<input type="checkbox"/>	AMPUTATION	<input type="checkbox"/>

(NA = Not Applicable)

Complications

(occurring since discharge from hospital)

Complication

New onset or worsening of angina	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Myocardial infarction	NO <input type="checkbox"/>	YES <input type="checkbox"/>
TIA / amaurosis fugax	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Stroke	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Haematoma (no surgical drainage required)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Haematoma (surgical drainage required)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Wound infection (requiring antibiotics)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Chest infection (requiring antibiotics)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Urine infection (requiring antibiotics)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
False aneurysm (not requiring surgical repair)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
False aneurysm (requiring surgical repair)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Surgical intervention for other complication	NO <input type="checkbox"/>	YES <input type="checkbox"/>

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
One-Month Clinical Follow-up Form**

Other (please specify):

PATIENT NUMBER

Patient Health

Since the last visit has the patient had:

Any in-patient hospital admissions? NO YES NUMBER

Episode 1

Date of admission: / (dd/mm/yy)

Date of discharge: / (dd/mm/yy)

Principal/main diagnosis: _____

Secondary/other diagnosis: _____

Surgical operations/procedures: _____

Episode 2

Date of admission: / (dd/mm/yy)

Date of discharge: / (dd/mm/yy)

Principal/main diagnosis: _____

Secondary/other diagnosis: _____

Surgical operations/procedures: _____

Episode 3

Date of admission: / (dd/mm/yy)

Date of discharge: / (dd/mm/yy)

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
One-Month Clinical Follow-up Form**

Principal/main diagnosis: _____

Secondary/other diagnosis: _____

Surgical operations/procedures: _____

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
One-Month Clinical Follow-up Form**

PATIENT NUMBER /

- Any day case admissions? NO YES NUMBER
- Any outpatient attendances? NO YES NUMBER
- Any GP consultations? NO YES NUMBER
- Any practice nurse consultations? NO YES NUMBER
- Any community nurse visits? NO YES NUMBER

Analgesia Requirement

Please record the patients analgesia requirements over the previous 48 hours:

Drug	Total Dose

Additional information:

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Clinical Follow-up Form**

PATIENT NUMBER

Clinical Follow-up Form

(To be completed by Research Nurse. Please complete text in BLOCK CAPITALS, tick the appropriate box or enter numbers into the boxes provided.)

Date of Assessment: / (dd/mm/yy)

Time of Assessment: 3/12 6/12 12/12

Recruiting Consultant: _____

Patient's Date of Birth: / Gender: MALE FEMALE
(dd/mm/yy)

Trial Leg: LEFT RIGHT

Date of Primary Intervention: / (dd/mm/yy)

Type of Primary Intervention: PTA SURGERY

Further Interventions: NONE PTA SURGERY AMPUTATION

Dates of Further Interventions: / /

Clinical status

Pulse:

Brachial blood pressure: Right: / Left: /

Ankle pressures in trial leg: *(insert not found [NF] if no signal insonated)*
for patients with compressible vessels record cuff pressure; for patients with incompressible ankle vessels record toe pressure or height (cm) above bed where Doppler signal lost (pole test)

	Cuff pressure	or	Height (cm) above bed
Dorsalis pedis	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Posterior tibial	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Perforating peroneal	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Toe pressure	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		

Ankle:brachial pressure index in trial leg = .
(highest ankle pressure/highest brachial pressure)

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Clinical Follow-up Form**

Patient Mobility

Independent Cane/Walker Prosthesis Wheelchair Bed-bound
PATIENT NUMBER ///

Pattern of tissue loss

Rest Pain:	ABSENT	<input type="checkbox"/>	IMPROVED	<input type="checkbox"/>	UNCHANGED	<input type="checkbox"/>
	WORSE	<input type="checkbox"/>	NA	<input type="checkbox"/>	AMPUTATION	<input type="checkbox"/>
Ulceration:	HEALED	<input type="checkbox"/>	IMPROVED	<input type="checkbox"/>	NO CHANGE	<input type="checkbox"/>
	WORSE	<input type="checkbox"/>	NA	<input type="checkbox"/>	AMPUTATION	<input type="checkbox"/>
Gangrene:	ABSENT	<input type="checkbox"/>	IMPROVED	<input type="checkbox"/>	NO CHANGE	<input type="checkbox"/>
	WORSE	<input type="checkbox"/>	NA	<input type="checkbox"/>	AMPUTATION	<input type="checkbox"/>

(NA = Not Applicable)

Patient Health

Since the last visit has the patient had:

Any in-patient hospital admissions? NO YES NUMBER

Episode 1

Date of admission: // (dd/mm/yy)

Date of discharge: // (dd/mm/yy)

Principal/main diagnosis: _____

Secondary/other diagnosis: _____

Surgical operations/procedures: _____

Episode 2

Date of admission: // (dd/mm/yy)

Date of discharge: // (dd/mm/yy)

Principal/main diagnosis: _____

Secondary/other diagnosis: _____

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Clinical Follow-up Form**

Surgical operations/procedures: _____

PATIENT NUMBER

Episode 3

Date of admission: (dd/mm/yy)

Date of discharge: (dd/mm/yy)

Principal/main diagnosis: _____

Secondary/other diagnosis: _____

Surgical operations/procedures: _____

Any day case admissions? NO YES NUMBER

Any outpatient attendances? NO YES NUMBER

Any GP consultations? NO YES NUMBER

Any practice nurse consultations? NO YES NUMBER

Any community nurse visits? NO YES NUMBER

Analgesia Requirement

Please record the patients analgesia requirements over the previous 48 hours:

Drug	Total Dose

Additional information:

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
In-patient Information Form**

PATIENT NUMBER

In-patient Information Form

(To be completed by Research Nurse. Please complete text in BLOCK CAPITALS, tick the appropriate box or enter numbers into the boxes provided.)

Date of Admission: / (dd/mm/yy)

Recruiting Consultant: _____

Patient's Date of Birth: Gender: MALE FEMALE
(dd/mm/yy)

Trial Leg: LEFT RIGHT

SECTION 1: Admission and Discharge Details

Date of hospital admission: /

Date of Baseline Assessment: /

Date of angiogram: /

Date of randomisation: /

Date of primary intervention: /

Date of further intervention:- /

Date discharged from hospital: /

Date of death: /

Total number of days* in hospital:

Total number of days* in ITU:

Total number of days* in HDU:

(* - to nearest half day)

Status on discharge: Alive Dead

Patient discharged to: Own home
Other acute hospital
Convalescent hospital
Nursing home
Other (specify) _____

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
In-patient Information Form**

PATIENT NUMBER

SECTION 3: Complications

(occurring during hospitalisation)

Complication

New onset or worsening of angina	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Myocardial infarction	NO <input type="checkbox"/>	YES <input type="checkbox"/>
TIA / amaurosis fugax	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Stroke	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Haematoma (no surgical drainage required)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Haematoma (surgical drainage required)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Wound infection (requiring antibiotics)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Chest infection (requiring antibiotics)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Urine infection (requiring antibiotics)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
False aneurysm (not requiring surgical repair)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
False aneurysm (requiring surgical repair)	NO <input type="checkbox"/>	YES <input type="checkbox"/>
Surgical intervention for other complication	NO <input type="checkbox"/>	YES <input type="checkbox"/>

Other (please specify):

Additional information:

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
In-patient Information Form**

PATIENT NUMBER

SECTION 4: Post-procedure clinical status

(to be completed at discharge or prior to secondary intervention, which ever is sooner).

Date of Assessment: (dd/mm/yy)

Brachial blood pressure: Right: Left:

Ankle pressures in trial leg: *(insert not found [NF] if no signal insonated)*
for patients with compressible vessels record cuff pressure: for patients with incompressible ankle vessels record toe pressure or height (cm) above bed where Doppler signal lost (pole test)

	Cuff pressure	or	Height (cm) above bed
Dorsalis pedis	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Posterior tibial	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Perforating peroneal	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		<input type="text"/> <input type="text"/> <input type="text"/> = <input type="text"/> <input type="text"/> <input type="text"/> mmHg
Toe pressure	<input type="text"/> <input type="text"/> <input type="text"/> mmHg		

Ankle:brachial pressure index in trial leg =
(highest ankle pressure/highest brachial pressure)

Rest Pain:	ABSENT	<input type="checkbox"/>	IMPROVED	<input type="checkbox"/>	UNCHANGED	<input type="checkbox"/>
	WORSE	<input type="checkbox"/>	NA	<input type="checkbox"/>	AMPUTATION	<input type="checkbox"/>
Ulceration:	HEALED	<input type="checkbox"/>	IMPROVED	<input type="checkbox"/>	NO CHANGE	<input type="checkbox"/>
	WORSE	<input type="checkbox"/>	NA	<input type="checkbox"/>	AMPUTATION	<input type="checkbox"/>
Gangrene:	ABSENT	<input type="checkbox"/>	IMPROVED	<input type="checkbox"/>	NO CHANGE	<input type="checkbox"/>
	WORSE	<input type="checkbox"/>	NA	<input type="checkbox"/>	AMPUTATION	<input type="checkbox"/>

(NA = Not Applicable)

Further intervention

Was there further intervention during this hospital admission NO YES

If YES:

Date of Further Intervention: (dd/mm/yy)

Type: PTA SURGERY AMPUTATION

Reason: COMPLICATION OF INTERVENTION

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
In-patient Information Form**

FAILURE OF INTERVENTION

OTHER

Timing: ELECTIVE EMERGENCY

Please complete relevant Further Intervention Form

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Surgery)**

PATIENT NUMBER

Intervention Form (Surgery)

(Please complete text in BLOCK CAPITALS, tick the appropriate box or enter numbers into the boxes provided. * - delete as necessary)

Date of Intervention: (dd/mm/yy)

Primary Intervention Further Intervention

If Further Intervention: date of Primary Intervention (dd/mm/yy)

Recruiting Consultant Surgeon: _____

Patient's Date of Birth: Gender: MALE FEMALE
(dd/mm/yy)

Trial Leg: LEFT RIGHT

SECTION 1: Surgery Details

(to be completed by the Consultant Surgeon please)

Time of arrival in anaesthetic room: : (hh:mm)

Time of start of anaesthetic procedures: : (hh:mm)

Time of start of operation: : (hh:mm)

Type of anaesthetic: GENERAL REGIONAL

Type of graft:

Vein: LEG ARM COMPOSITE
IN SITU REVERSED

PTFE / Dacron*: Externally reinforced: NO YES
+ Vein cuff / collar / boot* NO YES

Other (please specify): _____

Graft diameter: _____ mm

Was systemic heparin administered?: NO YES

Proximal anastomosis:

Distal anastomosis:

Common femoral artery Above knee popliteal artery

Deep femoral artery Below knee popliteal artery

Superficial femoral artery Posterior tibial artery (upper / middle / lower* third)

Above knee popliteal artery Anterior tibial artery (upper / middle / lower* third)

Below knee popliteal artery Peroneal artery (upper / middle / lower* third)

Dorsalis pedis

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Surgery)**

PATIENT NUMBER

Immediate outcome (in the opinion of the senior surgeon present):

The graft was running satisfactorily at the end of the procedure: NO YES

Was the operation combined with amputation:

NO DIGITS FOREFOOT TRANS-TIBIAL TRANS FEMORAL

Time of departure from theatre: : (hh:mm)

Time of departure from recovery room: : (hh:mm)

Human Resources

(please enter numbers of each grade of staff present)

Surgeons:

Consultant
Registrar
Senior House Officer
House Officer

Anaesthetist:

Consultant
Senior Registrar
Registrar
Senior House Officer

Nursing Staff:

Grade A
Grade C
Grade E
Grade G

Grade B
Grade D
Grade F

Technicians:

ODA/ODP

Additional information:

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Surgery)**

PATIENT NUMBER

SECTION 2: Surgical Materials

(to be completed by theatre staff nurse; please enter the numbers of each item used during the procedure)

Sutures:

Prolene 6/0 W8597	<input type="text"/> <input type="text"/>
Prolene 6/0	<input type="text"/> <input type="text"/>
Vicryl 3/0 9717	<input type="text"/> <input type="text"/>
Vicryl 2/0 9150	<input type="text"/> <input type="text"/>
Vicryl 2/0 tie 9044	<input type="text"/> <input type="text"/>
CV6	<input type="text"/> <input type="text"/>
CV5	<input type="text"/> <input type="text"/>

Trays:

Medium Basic Trays	<input type="text"/> <input type="text"/>
Arterial Limbneck	<input type="text"/> <input type="text"/>
Diathermy Tongs	<input type="text"/> <input type="text"/>
Diathermy Pad	<input type="text"/> <input type="text"/>
Diathermy Lead	<input type="text"/> <input type="text"/>
Vessel Retractor x2	<input type="text"/> <input type="text"/>
Embolectomy Catheter	<input type="text"/> <input type="text"/>
Needle holder	<input type="text"/> <input type="text"/>
Tunneling Tool	<input type="text"/> <input type="text"/>

Swabs and Gowns:

Gowns (disp) x 1	<input type="text"/> <input type="text"/>
Gowns (disp) x 3	<input type="text"/> <input type="text"/>
Gowns (linen) x 1	<input type="text"/> <input type="text"/>
Gowns (linen) x 3	<input type="text"/> <input type="text"/>
Swabs x 5 (Taped)	<input type="text"/> <input type="text"/>
Mepore Dressings	<input type="text"/> <input type="text"/>

Miscellaneous:

Suction Tubing	<input type="text"/> <input type="text"/>
Suction Catheters	<input type="text"/> <input type="text"/>
Opsite (Large)	<input type="text"/> <input type="text"/>
Irrigation Jet	<input type="text"/> <input type="text"/>
Discard-a-pad	<input type="text"/> <input type="text"/>
Masks	<input type="text"/> <input type="text"/>
Caps	<input type="text"/> <input type="text"/>
Sterile Gloves	<input type="text"/> <input type="text"/>

Additional Information / Equipment (excluding Scalpel Blades/Needles/Syringes and other items of nominal cost):

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Surgery)**

PATIENT NUMBER

SECTION 3: Medications in Theatre
(to be completed by the anaesthetist please)

Regional Block:

Drug Name	Dose / % per ampoule	No of amps used
Bupivacaine	0.25%/10ml	
	0.50%/10ml	
	0.75%/10ml	
Other:		

Anaesthetic Drugs:

Drug Name	Dose / % per ampoule	No of amps used
Propofol	200 mg	
Propofol pre-filled syringes	500 mg	
Thiopentone	250 – 500 mg	
Fentanyl	100 µg	
Alfentanyl	1 mg	
Morphine	10 mg	
Diamorphine	10 mg	
Vecuronium	10 mg	
Atracurium	50 mg	
Methoxamine	20 mg	
Ephedrine	30 mg	
Heparin	5000 units	
Ondasetron	4 mg	
Neostigmine	2.5 mg	
Glycopyrrolate	600 µg	
Atropine	0.6 mg	
Midazolam	10 mg	
Water	10 ml	
Saline	10 ml	

Other Drugs:

Temazepam (pre-med)	10 mg	
Cefuroxime	750 mg	
Other:		

Maintenance Anaesthetic:

Isoflurane	
Sevoflurane	
Propofol	
Other:	

O ₂	
N ₂ O	

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Surgery)**

PATIENT NUMBER

SECTION 3: Medications in Theatre (cont.)

Intravenous Fluids:

Type	Volume of Units	Number Given
Hartmanns Solution	500 ml	
Normal Saline	500 ml	
Gelofusine	500 ml	
Other:		

Type	Volume of Units	Number Given
PPS	400 ml	
Dextran 70	500 ml	
Blood		

Equipment and Disposables Used by Anaesthetist:

Item	Number
IV Giving Sets	
IV Cannula: Venflon	
Arterial Cannula:	
Vygon Ledercath	
Arrow	
Vasocan	
Quickcath	
Arterial Pressure Kit	
Tegaderm Dressing	
Lectrocath	
CVP Catheter Set	
Regional Block Pack	
Regional Block Needle	
Stimuplex Needle	
3-way Tap	
Other:	

Item	Number
Endotracheal Tube	
Guedel Airway	
Post-op Oxygen Mask	
Nasal Cannulae	
Epidural Pack	
Spinal Needle: 22G	
Spinal Needle: 24G Sprottie	
Laryngeal Mask Airway	
"Bair Hugger" Warmine Blanket	
Syringes: 50 ml; 20 ml	
Syringes: 10 ml; 5 ml; 2 ml	
Needles	
ECG Electrodes	
Sterile Gloves	

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (PTA)**

PATIENT NUMBER

Intervention Form (PTA)

(Please complete text in BLOCK CAPITALS, tick the appropriate box or enter numbers into the boxes provided.)

Date of Intervention: (dd/mm/yy)

Primary Intervention Further Intervention

If Further Intervention: date of Primary Intervention (dd/mm/yy)

Recruiting Consultant Radiologist: _____

Patient's Date of Birth: Gender: MALE FEMALE
(dd/mm/yy)

Trial Leg: LEFT RIGHT

SECTION 1: PTA Details

(to be completed by the Consultant Radiologist please)

Time of arrival in angio-room: : (hh:mm)

Time of start of procedure: : (hh:mm)

PTA 1

Intention to treat: INTIMAL SUB-INTIMAL

Treatment: INTIMAL SUB-INTIMAL

Arterial segment treated:

Superficial femoral artery

Posterior tibial artery

Above knee popliteal artery

Anterior tibial artery

Below knee popliteal artery

Peroneal artery

Type of disease treated:

Non-occlusive

Occlusive

Focal stenosis

Length of occlusion: _____ cm

Diffuse disease (<50% segment length)

Diffuse disease (>50% segment length)

Immediate outcome (in the opinion of the senior interventionalist):

Complete technical success

Technical failure

Failure to cross lesion

Distal embolism

Residual stenosis

Other

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (PTA)**

Residual dissection

PATIENT NUMBER

PTA 2

Intention to treat: INTIMAL

SUB-INTIMAL

Treatment: INTIMAL

SUB-INTIMAL

Arterial segment treated:

Superficial femoral artery

Posterior tibial artery

Above knee popliteal artery

Anterior tibial artery

Below knee popliteal artery

Peroneal artery

Type of disease treated:

Non-occlusive

Occlusive

Focal stenosis

Length of occlusion: _____ cm

Diffuse disease (<50% segment length)

Diffuse disease (>50% segment length)

Immediate outcome (in the opinion of the senior interventionalist):

Complete technical success

Technical failure

Failure to cross lesion

Distal embolism

Residual stenosis

Other

Residual dissection

PTA 3

Intention to treat: INTIMAL

SUB-INTIMAL

Treatment: INTIMAL

SUB-INTIMAL

Arterial segment treated:

Superficial femoral artery

Posterior tibial artery

Above knee popliteal artery

Anterior tibial artery

Below knee popliteal artery

Peroneal artery

Type of disease treated:

Non-occlusive

Occlusive

Focal stenosis

Length of occlusion: _____ cm

Diffuse disease (<50% segment length)

Segment occluded:

Diffuse disease (>50% segment length)

Immediate outcome (in the opinion of the senior interventionalist):

Complete technical success

Technical failure

Failure to cross lesion

Distal embolism

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (PTA)**

Residual stenosis

Other

Residual dissection

PATIENT NUMBER

Time of departure from angio-room:

: (hh:mm)

Time of departure from recovery room:

: (hh:mm)

Human Resources

(please enter numbers of each grade of staff present)

Radiologists:

Consultant

Registrar

Radiographers:

Superintendent

Senior 1

Senior 2

Basic

Nursing Staff:

Grade A

Grade C

Grade E

Grade G

Grade B

Grade D

Grade F

Additional information:

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (PTA)**

PATIENT NUMBER

SECTION 2: Materials
(to be completed by staff nurse please)

Equipment:

	Number		Number
Disposable pack	<input type="text"/> <input type="text"/>	Needles	<input type="text"/> <input type="text"/>
Intensifier cover	<input type="text"/> <input type="text"/>	Syringes – 2, 5, 10ml	<input type="text"/> <input type="text"/>
Lead Screen cover	<input type="text"/> <input type="text"/>	Syringes – 20, 50ml	<input type="text"/> <input type="text"/>
One-way taps	<input type="text"/> <input type="text"/>	Luer lock syringe	<input type="text"/> <input type="text"/>
Puncture needles	<input type="text"/> <input type="text"/>		
Guidewires	<input type="text"/> <input type="text"/>	Other (please specify):	<input type="text"/> <input type="text"/>
Catheter	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>
Inflation device	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>
Balloon catheter – small vessel	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>
Balloon catheter – large vessel	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>
Sheath	<input type="text"/> <input type="text"/>	_____	<input type="text"/> <input type="text"/>
Perclose	<input type="text"/> <input type="text"/>		
Angioseal	<input type="text"/> <input type="text"/>		
Vasoseal	<input type="text"/> <input type="text"/>		

Medications and Fluids

Drug Name	Dose/ % per ampoule or Volume of Units	No of amps or units used
Heparin	1000 U/ml	
Lignocaine		
Betadine		
Contrast (please specify):		
NaCl	500 ml	
Hypnovel		
Other (please specify):		

Was a post-PTA angiogram performed? NO YES

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Amputation)**

PATIENT NUMBER

Intervention Form (Amputation)

(Please complete text in BLOCK CAPITALS, tick the appropriate box or enter numbers into the boxes provided.)

Date of Amputation: (dd/mm/yy)

Date of Previous Intervention: (dd/mm/yy)

Recruiting Consultant: _____

Patient's Date of Birth: Gender: MALE FEMALE
(dd/mm/yy)

Trial Leg: LEFT RIGHT

Time of Last Follow-up: None 1/12 3/12 6/12

Date of Readmission: (dd/mm/yy)

SECTION 1: Amputation details

(to be completed by the Consultant Surgeon please)

Time of arrival in anaesthetic room: : (hh:mm)

Time of start of anaesthetic procedures: : (hh:mm)

Time of start of operation: : (hh:mm)

Type of anaesthetic: GENERAL REGIONAL

Leg amputated: LEFT RIGHT

Level of amputation: DIGITS FOREFOOT
TRANS-TIBIAL TRANS-FEMORAL

Time of departure from theatre: : (hh:mm)

Time of departure from recovery room: : (hh:mm)

Amputation at the trans-tibial or trans-femoral level constitute a primary end-point of the trial and further follow-up is no longer required.

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Amputation)**

Patients undergoing amputation of the digits or forefoot remain as trial participants and continue being followed-up.

PATIENT NUMBER

Human Resources

(please enter numbers of each grade of staff present)

Surgeons:

Consultant
Registrar
Senior House Officer
House Officer

Anaesthetist:

Consultant
Senior Registrar
Registrar
Senior House Officer

Nursing Staff:

Grade A
Grade C
Grade E
Grade G

Grade B
Grade D
Grade F

Technicians:

ODA/ODP

Additional information:

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Amputation)**

PATIENT NUMBER

SECTION 2: Surgical Materials

(to be completed by theatre staff nurse; please enter the numbers of each item used during the procedure)

Sutures:

Prolene 3/0	<input type="text"/> <input type="text"/>
Prolene 2/0	<input type="text"/> <input type="text"/>
Vicryl 1/0 ties	<input type="text"/> <input type="text"/>
Vicryl 2/0 tie 9044	<input type="text"/> <input type="text"/>
Silk 2/0	<input type="text"/> <input type="text"/>
Other	<input type="text"/> <input type="text"/>

Trays:

Medium Basic Trays	<input type="text"/> <input type="text"/>
Amputation	<input type="text"/> <input type="text"/>
Diathermy Tongs	<input type="text"/> <input type="text"/>
Diathermy Pad	<input type="text"/> <input type="text"/>
Diathermy Lead	<input type="text"/> <input type="text"/>
Diathermy Tip	<input type="text"/> <input type="text"/>

Swabs and Gowns:

Gowns (disp) x 1	<input type="text"/> <input type="text"/>
Gowns (disp) x 3	<input type="text"/> <input type="text"/>
Gowns (linen) x 1	<input type="text"/> <input type="text"/>
Gowns (linen) x 3	<input type="text"/> <input type="text"/>
Swabs x 5 (Taped)	<input type="text"/> <input type="text"/>
Swabs x 5 (10 x 10)	<input type="text"/> <input type="text"/>

Miscellaneous:

Redivac Drain	<input type="text"/> <input type="text"/>
Discard-a-pad	<input type="text"/> <input type="text"/>
Masks	<input type="text"/> <input type="text"/>
Caps	<input type="text"/> <input type="text"/>
Sterile Gloves	<input type="text"/> <input type="text"/>

Dressing (please specify type): _____

Additional Information / Equipment (excluding Scalpel Blades and other items of nominal cost):

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Amputation)**

PATIENT NUMBER / /

SECTION 3: Medications in Theatre
(to be completed by the anaesthetist please)

Regional Block:

Drug Name	Dose / % per ampoule	No of amps used
Bupivacaine	0.25%/10ml	
	0.50%/10ml	
	0.75%/10ml	
Other:		

Anaesthetic Drugs:

Drug Name	Dose / % per ampoule	No of amps used
Propofol	200 mg	
Propofol pre-filled syringes	500 mg	
Thiopentone	250 – 500 mg	
Fentanyl	100 µg	
Alfentanyl	1 mg	
Morphine	10 mg	
Diamorphine	10 mg	
Vecuronium	10 mg	
Atracurium	50 mg	
Methoxamine	20 mg	
Ephedrine	30 mg	
Heparin	5000 units	
Ondasetron	4 mg	
Neostigmine	2.5 mg	
Glycopyrrolate	600 µg	
Atropine	0.6 mg	
Midazolam	10 mg	
Water	10 ml	
Saline	10 ml	

Other Drugs:

Temazepam (pre-med)	10 mg	
Cefuroxime	750 mg	
Other:		

Maintenance Anaesthetic:

Isoflurane	
Sevoflurane	
Propofol	
Other:	

O ₂	
N ₂ O	

**Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) Trial
Intervention Form (Amputation)**

PATIENT NUMBER

SECTION 3: Medications in Theatre (cont.)

Intravenous Fluids:

Type	Volume of Units	Number Given
Hartmanns Solution	500 ml	
Normal Saline	500 ml	
Gelofusine	500 ml	
Other:		

Type	Volume of Units	Number Given
PPS	400 ml	
Dextran 70	500 ml	
Blood		

Equipment and Disposables Used by Anaesthetist:

Item	Number
IV Giving Sets	
IV Cannula: Venflon	
Arterial Cannula:	
Vygon Ledercath	
Arrow	
Vasocan	
Quickcath	
Arterial Pressure Kit	
Tegaderm Dressing	
Lectrocath	
CVP Catheter Set	
Regional Block Pack	
Regional Block Needle	
Stimuplex Needle	
3-way Tap	
Other:	

Item	Number
Endotracheal Tube	
Guedel Airway	
Post-op Oxygen Mask	
Nasal Cannulae	
Epidural Pack	
Spinal Needle: 22G	
Spinal Needle: 24G Sprottic	
Laryngeal Mask Airway	
"Bair Hugger" Warmine	
Blanket	
Syringes: 50 ml; 20 ml	
Syringes: 10 ml; 5 ml; 2 ml	
Needles	
ECG Electrodes	
Sterile Gloves	