

## **PLACEBO SURGERY: AN NHS-FUNDED TRIAL?**

## What do you as a surgeon think?

- The benefits of arthroscopic lavage (and/or debridement) for the management of knee osteoarthritis are unproven<sup>1</sup>.
- The NHS is considering funding a clinical trial to assess the effectiveness of arthroscopic lavage.
- · They are considering including a placebo arm within the trial.
- The possibility of a placebo has been discussed with groups of surgeons, anaesthetists, patients and ethics committee representatives.
- Informed by these discussions, the following placebo is being proposed:
  - General anaesthetic (as for arthroscopic lavage)
  - Three small skin incisions penetrating only the epidermis
  - No penetration of the knee space
- Arthroscopic lavage, placebo surgery and conservative management will be compared in terms of knee function, pain and quality of life.
- Our research group has been commissioned to find out what surgeons think of this, specifically:
  - Do you think the NHS should proceed with this trial?
  - What are your views on the plan for the trial?
  - Would you take part?
- Please take the time (approx. 2 minutes) to complete this questionnaire.
- The results of this survey will <u>directly</u> influence whether this trial will be conducted.

Q1.	If a trial of <b>arthroscopic lavage</b> vs <b>placebo surgery</b> vs <b>conservative</b> <b>management</b> were to be funded in the UK:	
	a) would you be supportive of such research being mounted?	Yes
		No
	b) would you consider taking part?	Yes
		No
	c) if a friend or member of your family had osteoarthritis of the knee and were asked to participate in this trial would you encourage them to	
	sign up for the trial?	Yes
		No

<sup>1</sup> Bandolier. Surgery for arthritic knee: roundup (2002). <u>http://www.jr2.ox.ac.uk/bandolier/booth/Arthritis/arthrokn.html</u>

Q2.	If a trial of <b>arthroscopic lavage</b> versus <b>conservative management placebo</b> ) were funded in the UK:	only (ie <b>no</b>
	a) would you be supportive of such research being mounted?	Yes No
	b) would you consider taking part?	Yes No
	c) if a friend or member of your family had osteoarthritis of the knee and were asked to participate in this trial would you encourage them to sign up for the trial?	Yes
		No

Q3.	If a placebo trial went ahead the randomisation between groups could be made equal
	(ie equal chance of allocation to arthroscopic lavage, placebo surgery, or conservative
	management) or unequal (ie randomisation loaded to favour allocation to active
	surgery). What do you think would be the best strategy?

Equal randomisation (1:1:1 allocation to arthroscopic lavage, placebo surgery, conservative management) Unequal randomisation (2:1:1 allocation to arthroscopic lavage, placebo surgery, conservative management)

No preference

Other randomisation ratio (please specify)

Q4.	Do you currently perform arthroscopic management of knee osteoarthritis?	lavage	(and/or	debridement) f	or the
				Ye	s
			I us	ed to, but not nov N	
	If you used to perform arthroscopic lavage to ( <i>please specify</i> ):	out do no	ot now, wl	ny did you stop?	

Q5. Do you have any other comments to make about this proposed research? (please use an additional sheet if required) Thank you for completing this questionnaire

Please return it in the envelope provided



## **PLACEBO SURGERY: AN NHS-FUNDED TRIAL?**

## What do anaesthetists think?

- The benefits of arthroscopic lavage (+/- debridement) for the management of knee osteoarthritis are unproven<sup>1</sup>.
- The NHS is considering funding a clinical trial to assess the effectiveness (in terms
  of knee function, pain and quality of life) of arthroscopic lavage.
- They are considering including a placebo surgery arm within the trial.
- The possibility of placebo surgery has been discussed with groups of surgeons, anaesthetists, patients and ethics committee representatives.
- Informed by these discussions, the following placebo is being proposed:
  - General anaesthetic (as for arthroscopic lavage)
  - Three small skin incisions penetrating only the epidermis
  - No penetration of the knee space
- Those who took part in the discussion groups thought general anaesthesia was most appropriate as it a) provided the best mimic for the full surgery and b) was thought to be the technique anaesthetists were most familiar with and most experienced in using (compared with a hypnotic and opioid-based sedation regimen as was used in a previous trial).
- Our research group has been commissioned to find out what anaesthetists think of this, specifically:
  - Do you think the NHS should proceed with this trial?
  - What are your views on the plan for the trial?
  - If the orthopaedic surgeon you work with wished to take part, would you
  - co-participate as an anaesthetist for the trial?
- Please take the time (approx. 2 minutes) to complete this questionnaire.
- The results of this survey will directly influence whether this trial will be conducted.

Q1.	If a trial of arthroscopic lavage vs placebo surgery vs conservative ma were to be funded in the UK:	anagement
	a) would you be supportive of such research being mounted?	Yes No
	b) if the orthopaedic surgeon you work with wished to take part, would you agree to co-participate as an anaesthetist for the trial?	Yes No
	c) if a friend or member of your family had osteoarthritis of the knee and were asked to participate in this trial, would you encourage them to sign up for the trial?	Yes No

Q2.	If a trial of <b>arthroscopic lavage</b> versus <b>conservative management</b> only were funded in the UK:	(ie <b>no placebo</b> )
	a) would you be supportive of such research being mounted?	Yes No
	b) if the orthopaedic surgeon you work with wished to take part, would you agree to co-participate as an anaesthetist for the trial?	Yes No
	c) if a friend or member of your family had osteoarthritis of the knee and were asked to participate in this trial, would you encourage them to sign up for the trial?	Yes No

Q3. If a placebo trial went ahead the randomisation between groups could be made equal equal chance of allocation to arthroscopic lavage, placebo surgery, or conserved management) or unequal (ie randomisation loaded to favour allocation to active surge What do you think would be the best strategy?         Equal randomisation (1:1:1 allocation to arthroscopic lavage, placebo surgery, conservative management)         Unequal randomisation (2:1:1 allocation to arthroscopic lavage, placebo surgery, conservative management)         No preference         Other randomisation ratio (please specify)		
conservative management) Unequal randomisation (2:1:1 allocation to arthroscopic lavage, placebo surgery, conservative management) No preference	equal chance of allocation to arthroscopic lavage, placebo surgery, or or management) or unequal (ie randomisation loaded to favour allocation to activ	onserva
conservative management) No preference		
Other randomisation ratio (please specify)	No preference	
	Other randomisation ratio (please specify)	

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Q4. Do you have any other comments to make about th	is proposed research? (please use an additional sheet if required)
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Thank you for completing this questionnaire Please return it in the envelope provided