

Inclusion and exclusion criteria

Protocol version 2 (approved 18.8.15, before recruitment started)

Inclusion criteria

1. Patients (18 years or over) who have a native AVF in the arm that has been used for haemodialysis for at least 12 dialysis sessions
2. An indication for a fistuloplasty as determined by the local clinical team
3. The access circuit is free of synthetic graft material or stents
4. A reduction of vessel diameter of $\geq 50\%$ measured angiographically, and a reference diameter of the outflow vein of at least 4 mm and less than the size of the largest available drug-coated balloon
5. A residual stenosis $\leq 30\%$ after plain balloon fistuloplasty

Exclusion criteria

1. Patient unable to give informed consent
2. Patient unwilling or unable to comply with all study-related procedures
3. Systemic or local (to the fistula) infection treated for less than 10 days prior to the study procedure
4. Synchronous venous lesion, with a reduction of vessel diameter of $\geq 50\%$ measured angiographically, in the same access circuit
5. Location of stenosis beyond the thoracic inlet
6. Thrombosed (failed) dialysis circuit at time of treatment
7. Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children, within two years of study treatment
8. Known hypersensitivity or contraindication to contrast medium which cannot be adequately premedicated
9. Known hypersensitivity or contraindication to paclitaxel

Protocol version 5 (approved 8.4.16)

Inclusion criteria 1 amended:

1. Patients (18 years or over) who have a native AVF in the arm

Protocol version 6 (approved 31.8.16)

Inclusion criteria 6 added:

6. A treatment segment, containing one or more lesions, which can be treated with ≤ 120 mm of a single drug-coated balloon.

Exclusion criteria 4 amended:

4. One or more lesions outside the treatment segment, with a reduction of vessel diameter of $\geq 50\%$ measured angiographically, in the same access circuit.

Protocol version 7 (approved 21.3.17)

Exclusion criteria 4 amended again:

4. One or more lesions outside the treatment segment, with a reduction of vessel diameter of $\geq 50\%$ measured angiographically, in the same access circuit. The patient will also be excluded if any lesions outside the treatment segment are treated even if these are $<50\%$