

Management of idiopathic anal fistula using collagen

Submission date 20/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/08/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/03/2012	Condition category Digestive System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Peter Lunniss

Contact details
Homerton University Hospital NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

Additional identifiers

Study information

Scientific Title
Management of idiopathic anal fistula using collagen: a prospective, randomised trial

Study objectives

Fibrin glue and porcine intestinal submucosa have been used as novel sphincter preserving techniques to heal anal fistulas, but the success of the former is highly variable, and widespread long term data are not available for the latter. The study aim was to assess the safety, feasibility and potential efficacy of another novel agent, cross-linked collagen, either as a solid implant or as fibres suspended in fibrin glue, to heal idiopathic anal fistulas.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the East London and the City Research Ethics Committee in September 2004 (ref: P/03/870)

Study design

Prospective randomised single-blind controlled study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Idiopathic anal fistulas deemed unsuitable for fistulotomy

Interventions

This is a randomised single-blind controlled study performed at two London (UK) hospitals, the Royal London Hospital and the Homerton University Hospital.

Intervention 1: Solid Permacol® implant

Intervention 2: Milled Permacol® fibres suspended in fibrin glue

Permacol® (Tissue Science Laboratories plc) is a porcine derived acellular dermal sheet, predominately composed of Type I collagen (93 - 95%), with type III collagen and a small amount of elastin comprising the remainder. Sterile sheets 1.0 mm in thickness were used in this study. The alternative format is a 2.5 ml Permacol injection® (Tissue Science Laboratories plc), a 60% (wet weight/volume) suspension in saline of the cryogenically milled implant, with a defined particle size of 150 µm in diameter.

Fibrin glue: The 1.0 ml Tisseel Kit® - Two Component Fibrin Sealant (Baxter Healthcare Ltd, UK) was employed.

The implant was fashioned to the approximate dimensions of the fistula tract, and drawn into position using a suture, passed along a grooved fistula probe within the fistula tract.

The fibre suspension was prepared as follows: 1 ml Permacol injection® was injected into a 1.5 ml sterile Eppendorf Biopur® pipette tip (Eppendorf UK Limited, UK), and centrifuged at 1,100 rpm for 5 minutes. The saline supernatant was discarded, and the residual collagen fibres re-suspended in 1.0 ml calcium chloride solution supplied with the Tisseel Kit®. The individual components of the Tisseel Kit® were mixed, warmed in a Fibrinotherm™ (Baxter AG, Austria) and were then drawn up into two syringes (syringe 1: fibrinogen and aprotinin; syringe 2: thrombin and collagen fibres suspended in calcium chloride solution), which were subsequently placed in a Duploject™ (Baxter AG) two-syringe clip, where they shared a common plunger. A plastic double-lumen Y-connector joined these two syringes. This apparatus was then attached to a 21-gauge cannula, passed along a grooved fistula probe in the fistula tract.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Collagen

Primary outcome(s)

1. Safety of procedure, defined as no acute perineal sepsis or anal incontinence at 3 months post intervention. Assessed by symptom and continence questionnaires, clinical examination, anal manometry, and endoanal ultrasound. All performed at 3 months post-intervention.
2. Success of procedure assessed by symptom questionnaire and clinical examination at 3, 6, 9, 12 and 18-months post-intervention

Key secondary outcome(s)

The following were assessed by a patient questionnaire at 3-months post-intervention:

1. Time taken for perineal wound to heal
2. Time taken to return to work

Completion date

01/05/2008

Eligibility

Key inclusion criteria

All patients, over 18-years, with an idiopathic anal fistula, under the care of a single surgeon, in whom fistulotomy was deemed unsuitable (on the basis of the fistula type and level, threat to continence or patient choice).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Patients with either clinical or radiological (magnetic resonance imaging) evidence of secondary tracts or acute sepsis were excluded from the trial until these had been eradicated, leaving a single primary tract.

Date of first enrolment

01/09/2004

Date of final enrolment

01/05/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Homerton University Hospital NHS Foundation Trust

London

United Kingdom

E9 6SR

Sponsor information

Organisation

Queen Mary, University of London (UK)

ROR

<https://ror.org/026zzn846>

Funder(s)

Funder type

Government

Funder Name

Local NHS Trusts (UK) - the trial was performed on NHS patients requiring a surgical intervention at their local trusts

Funder Name

Tissue Science Laboratories plc (UK) - donated Permacol® unconditionally

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2011		Yes	No