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Management of idiopathic anal fistula using collagen

Submission date	Recruitment status	[_] Prospectively registered
20/06/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/08/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/03/2012	Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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
Intevention 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 measure
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 peformed 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

Secondary outcome measures
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

Overall study start date
01/09/2004

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

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
England

United Kingdom

Study participating centre
Homerton University Hospital NHS Foundation Trust
London
United Kingdom
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Sponsor information

Organisation
Queen Mary, University of London (UK)

Sponsor details
c/o Mr P J Lunniss
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Sponsor type
University/education

Website
http://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Government

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

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

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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