# Management of idiopathic anal fistula using collagen

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

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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 resuspended 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

 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.
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 E9 6SR

## Sponsor information

**Organisation** Queen Mary, University of London (UK)

#### Sponsor details

c/o Mr P J Lunniss Centre for Academic Surgery Institute of Cell & Molecular Science Barts & The London NHS Trust London United Kingdom 1BB UK p.j.lunniss@qmul.ac.uk

**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?
<u>Results article</u>	results	01/01/2011		Yes	No