

The value of plugging percutaneous biliary drain tracts following drain removal

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 21/03/2017	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Clive Kay

Contact details
Radiology Department
Bradford Royal Infirmary
Duckworth Lane
Bradford
United Kingdom
BD9 6RJ
+44 (0)1274 364321
kaycl44@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0050153127

Study information

Scientific Title

The value of plugging percutaneous biliary drain tracts following drain removal

Study objectives

1. Does the use of medical collagen ('LYOSTYPT') stop bile leak following removal of percutaneous biliary drains?
2. Does the prevention of bile leak lead to a decrease in complications such as pain, fever and raised inflammatory markers?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

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 to request a patient information sheet

Health condition(s) or problem(s) studied

Obstructive jaundice

Interventions

Patients with obstructive jaundice not amenable to endoscopic treatment (primary investigation and treatment modality) referred for:

PTC (percutaneous transhepatic cholangiography)

+/- External percutaneous drain

+/- Internal drainage (stent) as a one stage procedure.

Wait for bilirubin to fall, temperature to settle and biliary tree to decompress. Patients re-attend the radiology department for drain removal.

Randomisation to drain tract plugged with collagen or drain not plugged.

Follow-up on ward by research nurses days 1, 2, 3 and 5 (both groups).

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Medical collagen

Primary outcome measure

1. Pain score after drain removal
2. Complication rate

Secondary outcome measures

Not provided at time of registration

Overall study start date

11/10/2004

Completion date

01/07/2005

Eligibility**Key inclusion criteria**

Patients already identified as requiring radiological intervention for life-threatening biliary obstruction

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

30 patients: 15 patients will be recruited for the tract plugging process and 15 for the non tract plugging

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

11/10/2004

Date of final enrolment

01/07/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Bradford Royal Infirmary

Bradford

United Kingdom

BD9 6RJ

Sponsor information

Organisation

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Bradford Teaching Hospitals NHS Foundation Trust (UK)

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