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The value of plugging percutaneous biliary drain tracts following drain removal

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 21/03/2017	**Condition category** Digestive System	

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
1. Pain score after drain removal
2. Complication rate

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Study participating centre
Bradford Royal Infirmary
Bradford
United Kingdom
BD9 6RJ

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Bradford Teaching Hospitals NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration