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The use of intravesical lignocaine to reduce pain and increase dwell time of intravesical mitomycin chemotherapy

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
13/02/2018	Cancer	[ ] Record updated in last year

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
N0077120719

Study information

Scientific Title
The use of intravesical lignocaine to reduce pain and increase dwell time of intravesical mitomycin chemotherapy

Study objectives
Does intravesical lignocaine reduce the pain and maximise the dwell time of intravesical mitomycin?

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Analgesia for intravesical mitomycin chemotheapy

Interventions
30 min before mitomycin is instilled into the patients bladder, 40 ml 0.5% lignocaine or 40 ml saline (placebo) will be instilled. The catheter will then be clamped. After 30 min, the lignocaine /placebo will be drained and mitomycin instilled. Visual analogue scores of pain will be taken at 30, 60 and 120 min (or at first void if sooner). The time that the mitomycin is tolerated will be noted.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mitomycin, lignocaine

Primary outcome measure
Visual analogue pain scores. Dwell time.

Secondary outcome measures
Not provided at time of registration

Overall study start date
10/03/2003

Completion date
10/11/2003

Eligibility

Key inclusion criteria
Patients with transitional cell carcinoma of the bladder, following their first endoscopic resection.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
10/03/2003

Date of final enrolment
10/11/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southern Derbyshire Acute Hospitals NHS Trust
Derby
United Kingdom
DE22 3NE

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Charity

Funder Name
Southern Derbyshire Acute Hospitals NHS Trust (NHS R&D Support Funding) + charitable funds

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