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

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