

Randomised controlled prospective clinical trial to evaluate the effectiveness of Ametop cream as an adjunctive analgesic agent in extracorporeal shock wave lithotripsy

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/03/2014	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0263152091

Study information

Scientific Title

Study objectives

Can cream be used as an adjunct to diclofenac in patients undergoing lithotripsy?

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)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Urological and Genital Diseases: Lithotripsy

Interventions

1. Pre treatment cream
2. No pre treatment cream

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ametop

Primary outcome measure

Visual analogue score of pain and measure of maximum shock intensity achieved during treatment session

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2003

Completion date

31/07/2007

Eligibility**Key inclusion criteria**

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100 patients from Urology

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2003

Date of final enrolment

31/07/2007

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

Department of Urology and Nephrology
London
United Kingdom
W1P 7PN

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

UCL Hospitals NHS Foundation Trust (UK)

Funder Name

NHS R&D Support Funding

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