ISRCTN56273457 https://doi.org/10.1186/ISRCTN56273457

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

Registration date
30/09/2005

Overall study status
Completed

Last Edited
13/03/2014

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] 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
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
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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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