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Effect of analgesia using buccal fentanyl versus diclofenac suppository for extracorporeal shock wave lithotripsy

Submission date
04/04/2012

Recruitment status
No longer recruiting

Registration date
06/11/2013

Overall study status
Completed

Last Edited
30/09/2016

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Extracorporeal shock wave lithotripsy (ESWL) is the name of the treatment that breaks down kidney stones into smaller pieces that can then be passed out in urine. The treatment can be painful. Rectal diclofenac is one of the common pain killers used for ESWL in the UK. Our goal is to find out what works better: oral diclofenac or buccal fentanyl (in the mouth). We are intending to assess the discomfort experienced by the patient before, during and after the treatment. We also intend to record any side effects and complications of analgesia used.

Who can participate?
We are intending to recruit 80-100 patients undergoing ESWL treatment in the Bedford Hospital (UK).

What does the study involve?
All the patients undergoing ESWL treatment in Bedford Hospital will be randomly allocated to one of two groups: they will either receive diclofenac suppository or buccal fentanyl as analgesia prior to the treatment. All participating patients will be asked to quantify the discomfort during, throughout and after the treatment. All side effects will be documented. Results will subsequently be compared between the two groups in the study.

What are possible benefits and risks of participating?
There will be no immediate benefit to those taking part. Following the study completion we will be able to draw conclusions whether buccal fentanyl analgesia is more efficient and safer for the patients undergoing ESWL treatment. Any potential risks are related to potential side effects of diclofenac and fentanyl. However, there is no increased risk to the patients as both oral diclofenac and buccal fentanyl are well established and widely used as analgesia is vital part of ESWL treatment.

Where is the study run from?
The study has been set up in Urology Department of Bedford Hospital NHS Trust.

When is the study starting and how long is it expected to run for?
We anticipate the study to start in July 2012 and run for 12 months or until 100 participants is recruited.

Who is funding the study?
Urology Department Bedford Hospital NHS Trust (UK)

Who is the main contact?
Mr Aasem Chaudry
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Contact information

Type(s)
Scientific

Contact name
Mr Aasem Chaudry

Contact details
Bedford Hospital NHS Trust
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Bedford
United Kingdom
MK42 9DJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Open-label randomised controlled study of efficacy of buccal fentanyl versus diclofenac suppository analgesia for extracorporeal shock wave lithotripsy

Study objectives
To assess the efficacy of buccal fentanyl use as analgesia for extracorporeal shock wave lithotripsy.
Pain associated with extracorporeal shock wave lithotripsy treatment is due to repetitive shockwave applied to body surface. Various analgesic agents are used worldwide. Diclofenac is

widely established. Buccal fentanyl is supposed to have a quicker mode of action due to buccal mucosal absorption and be potentially better tolerated due to lack of gastrointestinal side effects.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised single blind 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
Pain associated with extracorporeal shock wave lithotripsy treatment is due to repetitive shockwave applied to body surface.

Interventions
Randomised single-blind controlled trial comparing two interventions - buccal fentanyl versus oral diclofenac analgesia for ESWL.
One group will receive 100mcg of buccal fentanyl and second group will receive 100mg of oral diclofenac.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Diclofenac, fentanyl

Primary outcome measure
Pain measured on Visual Analogue Scale score (0= No pain, 10=Unbearable pain)

Secondary outcome measures
Presence of adverse reactions to buccal fentanyl or oral diclofenac

Overall study start date
01/08/2012

Completion date
01/03/2013

Eligibility

Key inclusion criteria
Patients undergoing extracorporeal shock wave lithotripsy in Bedford Hospital NHS Trust

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patient's refusal to be included in the trial
2. Allergy or adverse reaction to fentanyl or diclifenac
3. Contraindications to fentanyl or diclofenac

Date of first enrolment
01/08/2012

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Bedford Hospital NHS Trust
Bedford
United Kingdom
MK42 9DJ

Sponsor information

Organisation
Bedford Hospital NHS Trust (UK)

Sponsor details
Kempston Road
Bedford
England
United Kingdom
MK42 9DJ

Sponsor type
Hospital/treatment centre

Website
http://www.bedfordhospital.nhs.uk/

ROR
https://ror.org/031nbgr73

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Bedford Hospital NHS Trust

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