

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

<b>Submission date</b> 04/04/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/11/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 30/09/2016	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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## Additional identifiers

### Protocol serial number

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

Presence of adverse reactions to buccal fentanyl or oral diclofenac

**Completion date**

01/03/2013

**Eligibility****Key inclusion criteria**

Patients undergoing extracorporeal shock wave lithotripsy in Bedford Hospital NHS Trust

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

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

**Date of first enrolment**

01/08/2012

**Date of final enrolment**

01/03/2013

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Bedford Hospital NHS Trust**

Bedford

United Kingdom

MK42 9DJ

**Sponsor information****Organisation**

Bedford Hospital NHS Trust (UK)

**ROR**

<https://ror.org/031nbgr73>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Bedford Hospital NHS Trust

**Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration