# The efficacy of oral transmucosal fentamyl as an analgesic agent during pan retinal photocoagulation

Submission date Recruitment status Prospectively registered 28/09/2007 No longer recruiting [ ] Protocol Statistical analysis plan Registration date Overall study status 28/09/2007 Completed [X] Results [ ] Individual participant data **Condition category** Last Edited 18/10/2011 **Eve Diseases** 

### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

Mr David Ian Clark

#### Contact details

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#### Additional identifiers

Protocol serial number N0025180535

# Study information

Scientific Title

#### **Study objectives**

Study hypothesis amended as of 09/05/2008:

Diabetic retinopathy is the commonest cause of blindness and visual impairment in the working age group in the United Kingdom. Argon laser peripheral retinal scatter photocoagulation (PRP) is a commonly performed ophthalmic procedure which is used to treat diabetic retinopathy and other retinal vascular disease. It forms the mainstay of treatment of proliferative diabetic retinopathy, and is supported by a large evidence base.

#### Aims:

- 1. To evaluate the analgesic effect of oral transmucosal fentanyl citrate (OTFC) during pan retinal photocoagulation (PRP), compared with placebo
- 2. To determine the side effect profile of OTFC in opiate naive patients undergoing PRP

Study aim provided at time of registration:

To determine whether oral transmucosal fentanyl provides effective pain relief during peripheral retinal laser photocoagulation.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Sefton Local Research Ethics Committee. Date of approval: 190/06/2006 (ref: 06/Q1501/64-3)

#### Study design

Prospective, randomised, double-masked, crossover, pilot, single-centre trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Diabetic retinopathy

#### **Interventions**

Please note that, as of 09/05/2008, the start and anticipated end dates of this trial were updated from 01/05/2006 and 01/08/2007 to 01/09/2006 and 01/12/2007, respectively.

#### Interventions amended as of 09/05/2008:

Patients will be divided into two groups. Stratified randomisation into two groups of 19 will be generated by a using a random number table. Randomisation will be concealed by the pharmacy department until the trial is complete. The medication will be stored in the hospital pharmacy, and collected and signed for by nursing staff on a patient by patient basis.

Each patient will receive appropriate laser treatment divided equally over two separate visits (approximately 1,500 burns per visit). At each visit, each patient will be given a lollipop to suck for 30 minutes prior to commencement of laser treatment. The contents of the lollipop will be double-masked. Patients in one group will receive the placebo lollipop at the first visit and the treatment lollipop containing transmucosal fentanyl (200 mcg) at the second visit. Patients in the second group will receive the treatment lollipop at the first visit and placebo at the second

(cross-over). The two visits will be 1 week apart.

Following each treatment, the patient will complete a visual analogue pain score and side effect questionnaire relating to that visit.

Interventions provided at time of registration:

Prospective randomised double-masked crossover pilot trial comparing oral transmucosal fentanyl 200 mcg vs placebo. Patients divided into 2 groups. Stratified randomisation into 2 groups of 19 using random number table. All patients receive laser treatment appropriate to clinical needs, and complete pre-study questionnaire. At each of 2 visits patients will be given a lollipop to suck for 30 minutes prior to laser treatment, the content of the lollipop will be masked. Following each treatment the patient will complete a visual analogue pain score and side effect questionnaire.

#### Intervention Type

Drug

#### **Phase**

**Not Specified** 

#### Drug/device/biological/vaccine name(s)

transmucosal fentamyl

#### Primary outcome(s)

Added as of 09/05/2008:

- 1. Visual analogue pain score (100 mm) for each patient, after each laser treatment session
- 2. Side effect questionnaire for each patient, after each laser treatment session

#### Key secondary outcome(s))

Added as of 09/05/2008:

1. Calculation of the mean and standard deviation of outcome measurements

#### Completion date

01/12/2007

# **Eligibility**

#### Key inclusion criteria

Added as of 09/05/2008:

- 1. Both males and females
- 2. Patients undergoing pan retinal photocoagulation (PRP) for any reason:
- 2.1. Pan retinal/sectoral
- 2.2. One/both eyes

NB: Previous laser treatment to the same eye is not an exclusion criteria

#### Participant type(s)

Patient

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

**Not Specified** 

#### Key exclusion criteria

Added as of 09/05/2008:

- 1. Age < 18 years
- 2. Morphine/codeine allergy
- 3. Chronic obstructive pulmonary disease/emphysema
- 4. Mental incapability to provide informed consent
- 5. Concomitant or recent (within 2 weeks) use of monoamine oxidase inhibitors (MAOIs)

#### Date of first enrolment

01/09/2006

#### Date of final enrolment

01/12/2007

#### Locations

#### Countries of recruitment

United Kingdom

England

# Study participating centre Ophthalmology

Liverpool United Kingdom

L9 1AE

# Sponsor information

#### Organisation

Aintree University Hospitals NHS Foundation Trust (UK)

#### **ROR**

https://ror.org/02h67vt10

# Funder(s)

#### Funder type

Government

#### Funder Name

a. Aintree University Hospitals NHS Foundation Trust (UK)

#### Funder Name

b. Cephalon Ltd (UK), providing transmucosal fentanyl citrate and placebo lozenges

#### Funder Name

c. NHS R&D Support Funding (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2009		Yes	No