

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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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)

Primary study design

Interventional

Study design

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

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 fentanyl

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