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

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

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Added as of 09/05/2008:
1. Calculation of the mean and standard deviation of outcome measurements

Overall study start date
01/09/2006

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

Age group
Adult

Sex
Not Specified

Target number of participants
38

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
England

United Kingdom

Study participating centre

Ophthalmology
Liverpool
United Kingdom
L9 1AE

Sponsor information

Organisation
Aintree University Hospitals NHS Foundation Trust (UK)

Sponsor details
Research and Development Directorate
University Hospital Aintree
Longmoor Lane
Liverpool
England
United Kingdom
L9 7AL

Sponsor type
Hospital/treatment centre

Website
http://www.aintreehospitals.nhs.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

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

Study outputs

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