ISRCTN40332511 https://doi.org/10.1186/ISRCTN40332511

A pilot study to evaluate the use of pregabalin in the management of burning mouth syndrome

Submission date 16/04/2008	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/08/2008	**Overall study status** Stopped	
Last Edited 05/04/2012	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Alison Loescher

Contact details
School of Clinical Dentistry
Claremont Cresent
Sheffield
United Kingdom
S10 2TA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
STH 13781

Study information

Scientific Title

Study objectives
An open label study to evaluate the use of pregabalin in managing patients with burning mouth syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North Sheffield Research Ethics Committee. Date of approval: 19/07/2004 (ref: 04/q2308/57)

Study design
Single-arm, open label, pilot study.

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please contact Mrs J Parkin at j.a.parkin@sheffield.ac.uk for trial details.

Health condition(s) or problem(s) studied
Burning mouth syndrome

Interventions
The 12-week intervention is in four stages:

Stage 1: Pregabalin (oral), two weeks at 75 mg twice a day (bd)
Stage 2: Either maintain 75 mg bd or increase to 150 mg bd for a further 2 weeks
Stage 3: Either maintain the previous dose or increase (150 mg/ 300 mg bd) for a further 2 weeks
Stage 4: Maintain the previous dose or consider increase (150 mg/ 300 mg bd) for a further 6 weeks

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Pregabalin

Primary outcome measure
The following will be assessed pre-visit and at 2, 4, 6, and 12 weeks:
1. Severity of symptoms, assessed by a visual analogue scale (VAS)
2. Global impression of change

Secondary outcome measures
Medication side effects, recorded until 12 weeks.

Overall study start date
01/06/2005

Completion date
31/12/2008

Reason abandoned (if study stopped)
"Participant recruitment issue"

Eligibility

Key inclusion criteria
1. Both males and females
2. Adults (over 16)
3. Diagnosis of burning mouth syndrome

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. Reduced renal function
2. Females who are pregnant or breast feeding
3. Patients already taking anti-convulsants or anti-depressants
4. Hereditary problems of galactose intolerance, lapp lactase deficiency and glucose-galactose malabsorption

Date of first enrolment
01/06/2005

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Clinical Dentistry
Sheffield
United Kingdom
S10 2TA

Sponsor information

Organisation
Sheffield Teaching Hospitals NHS Foundation Trust (UK)

Sponsor details
Research Department
3rd Floor
Pegasus House
463a Glossop Road
Sheffield
England
United Kingdom
S10 2QD

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Industry

Funder Name
Educational grant from Pfizer (USA)

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