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Assessment of controlled release buccal inserts containing pilocarpine hydrochloride: a multi-centre, double-blind, placebo-controlled, randomised, cross-over study in patients diagnosed with Sjögren's Syndrome

Submission date
23/09/2002

Recruitment status
No longer recruiting

Registration date
23/09/2002

Overall study status
Completed

Last Edited
24/05/2016

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr John Hamburger

Contact details
The University of Birmingham
School of Dentistry
St Chad's Queensway
Birmingham
United Kingdom
B4 6NN
+44 (0)121 237 2888
j.hamburger@bham.ac.uk

Additional identifiers

Protocol serial number
PILO-BUC-002

Study information

Scientific Title
Assessment of controlled release buccal inserts containing pilocarpine hydrochloride: a multi-centre, double-blind, placebo-controlled, randomised, cross-over study in patients diagnosed with Sjögren's Syndrome

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Multi-centre double-blind placebo-controlled randomised cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Sjögren's Syndrome

Interventions
This trial is a 'cross-over' study with four treatment cycles. For each treatment cycle, patients will be provided with 12 buccal inserts, containing one of the following: 2.5, 5 or 10 mg pilocarpine or placebo. A treatment cycle is four days long, however, there will be a three day washout period between each new dose. The buccal insert is a hydrogel polymer with pilocarpine dispersed throughout the matrix. Each buccal insert should be inserted high in the upper buccal sulcus between the buccal mucosa and gingivae towards the back of the mouth and remain in situ for at least three hours. One buccal insert should be inserted three times daily in the period between meals.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
31/12/2002

Eligibility

Key inclusion criteria
Approximately 30 patients with primary or secondary Sjögren's Syndrome, as diagnosed by the modified European Diagnostic Classification, will be enrolled into the study, to accrue 25 evaluable patients

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2002

Date of final enrolment
31/12/2002

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The University of Birmingham
Birmingham
United Kingdom
B4 6NN

Sponsor information

Organisation
Controlled Therapeutics (Scotland) Ltd

ROR
https://ror.org/03e9kb581

Funder(s)

Funder type
Industry

Funder Name
Controlled Therapeutics (Scotland) Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration