ISRCTN32677164 https://doi.org/10.1186/ISRCTN32677164

A randomised clinical trial of the efficacy of topical and systemic treatment on recurrent oral ulcers

Submission date
02/03/2018

Recruitment status
No longer recruiting

Registration date
15/04/2018

Overall study status
Completed

Last Edited
04/10/2023

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Recurrent Aphthous Stomatitis (RAS, also called recurrent oral ulcers), is a common condition that affects up to 10% of the population. Affected patients will have crops of ulcers in their mouth appearing and disappearing spontaneously every so often. The ulcers can be severe sometimes and can cause pain. There are medications that can control these ulcers including prescribed steroid mouthwashes.
This study aims to investigate the effect of steroid mouthwash and Colchicine tablets, used individually and combined to treat ulcers. It also aims to determine the treatment period needed for optimum improvement in RAS.

Who can participate?
Adults aged 18 – 65 years with recurrent aphthous stomatitis (RAS)

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group use Betamethasone sodium phosphate mouthwash for three minutes then discarded, administered four times a day when ulcers are present and twice a day in between ulcer attacks.
Those in group 2 take a Colchicine 500 mcg tablet once daily after breakfast.
Those in the third group take a Colchicine 500 mcg tablet once daily and Betamethasone sodium phosphate mouth rinse for three minutes, four times a day during ulcer attacks only.
All participants are reviewed and assessed at the hospital every three months (five visits in total) and have the following measures taken: history, oral examination, Ulcer Severity Score, medication details, analysis of daily diary, side effects, blood and saliva samples, weight and blood pressure.

What are the possible benefits and risks of participating?
Participants benefit from having therapy for their ulcers and regular assessment of their mouth (at three months intervals for one year). There are no direct risks associated with participation in

the study.
Where is the study run from?
Guy's Hospital (UK)

When is the study starting and how long is it expected to run for?
July 2010 – April 2013

Who is funding the study?
Guys and St Thomas' NHS Trust

Who is the main contact?
Dr Anwar Tappuni (Public)
a.r.tappuni@qmul.ac.uk

Contact information

Type(s)
Public

Contact name
Dr Anwar Tappuni

ORCID ID
http://orcid.org/0000-0002-5370-2423

Contact details
Institute of Dentistry
Barts and The London School of Medicine and Dentistry
Queen Mary University of London
Turner Street
London
United Kingdom
E1 2AD
+44 (0)20 7882 8655
a.r.tappuni@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
06/Q0704/156

Study information

Scientific Title

Comparison of the efficacy of topical betamethasone, systemic colchicine and a combination of both therapies on the severity of recurrent aphthous stomatitis: a randomised clinical trial

Study objectives
Dual therapy with Colchicine tablets and Betamethasone mouthwash is more effective for RAS that monotherapy with either agents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
King's College Research Ethics Committee, 20/03/2007, ref: 06/Q0704/156

Study design
Randomised prospective parallel group single-center clinical trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Aphthous stomatitis

Interventions
Participants are randomly allocated to one of three groups by the clinical trial pharmacist according to a table specifically designed for the trial by a statistician at King's College London.
Group 1: Participants are prescribed Betamethasone sodium phosphate mouthwash made up by dissolving 500 mcg tablet in 10ml of water and used as a mouth rinse for 3 minutes then discarded, administered four times a day when ulcers are present and twice a day in between ulcer attacks.
Group 2: Participants are prescribed Colchicine 500 mcg tablets to be taken once daily after breakfast.
Group 3: Participants are prescribed Colchicine 500 mcg tablets once daily and Betamethasone sodium phosphate 500 mcg tablet dissolved in 10 ml of water and used as a mouth rinse for 3 minutes then discarded, four times a day during ulcer attacks only.
All participants are reviewed and assessed at the hospital every three months (five visits) and have the following measures taken: history, oral examination, Ulcer Severity Score, medication details, analysis of daily diary, side effects, blood and saliva samples, weight and blood pressure.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Betamethasone and Colchicine

Primary outcome measure
Ulcer severity is measured by a clinician using the Ulcer Severity Score (USS) at baseline, 3, 6, 9 and 12 months,

Secondary outcome measures
The level of nine specific cytokines (IL-2, IL-4, IL-5, IL-6, IL-8, IL-10, IL-17, TNF-a and TNF-g) are measured in serum and saliva samples using Fluorokine Multi-Analyte Profiling systems Human Base Kit A in relation to the USS at baseline, 3, 6, 9 and 12 months.

Overall study start date
06/07/2010

Completion date
07/04/2013

Eligibility

Key inclusion criteria
1. Diagnosed with RAS (defined as recurrent oral ulcers of unknown aetiology characterised by the spontaneous emergence of more than two bouts of oral ulcers per year, not associated with ulcers elsewhere in the body or with an underlying systemic abnormality).
2. Aged between 18-65 years.
3. Willing and able to give informed consent to participate in the study.
4. Not involved in other studies that would compromise their safety or undermine the scientific basis of the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Unable to give informed consent.
2. Unwilling or unable to comply with the study protocol.
3. Pregnant or breast feeding.
4. Atopic or have severe or relevant history of allergy, hypersensitivity or side effects to any of the study medications.
5. Diagnosed with systemic diseases thought to overlap with RAS i.e. Behcet's disease, HIV, haematological deficiencies, gastrointestinal or dermatological disorders.
6. Patients with a current or past history of cardiac, renal,or hepatic disease.
7. Patients who were on any type of local or systemic Steroids or on Colchicine currently or in the previous three months.
8. Patients who are debilitated in any way.

Date of first enrolment
01/12/2010

Date of final enrolment
03/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guys and St Thomas NHS Trust

Sponsor details
St Thomas Street
London
England

United Kingdom
SE1 9RT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Guys and St Thomas NHS Trust

Results and Publications

Publication and dissemination plan
Scientific conferences' presentations and scientific journals articles.

Intention to publish date
26/10/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Stephen Challacombe (Stephen.challacombe@kcl.ac.uk)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/10/2023	04/10/2023	Yes	No