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Understanding the role of Cyclosporin A drops in control of ocular inflammation in acute cases of Stevens Johnson Syndrome

Submission date
13/05/2016

Recruitment status
No longer recruiting

Registration date
03/10/2016

Overall study status
Completed

Last Edited
03/10/2016

Condition category
Skin and Connective Tissue Diseases

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

Plain English summary of protocol

Background and study aims (to set the scene)
Stevens Johnson Syndrome (SJS) is a serious, but rare, disorder of the skin and mucous membranes. It is usually caused by taking a particular medicine or in response to a infection. Patients usually first experience flu-like symptoms, followed by skin pain, facia and tongue swelling, a skin rash, blisters on the skin and mucous membranes of the nose, eyes and genitals and shedding of the skin. Acute ocular inflammation (inflammation of the middle layer of the eye) in SJS is present between 43%-81% of patients and up to 35% of them may experience permanent damamge to their sight. In order to prevent as much damage to a patients sight as possible, prevention of ocular complications (complications connected to the eyes or vision) is vital. Systemic steroids have been used in the past but these can cause significant side effects and can result in secondary infections. The aim of this study is to test how effective cyclosporine (a drug that supresses the immune system) is at controlling acute ocular inflammation in patients with SJS.

Who can participate?
Patients suffering from acute SJS.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are treated with cyclosporine eye drops as well as standard treatment for SJS; this includes topical antibiotics (eye drops), frequent lubrication of the eyes in the form of artificial tears and eye ointment. The eyes are also washed daily with saline.Patients in group 2 are treated only with topical antibiotics, frequent lubrication of the eyes in the form of artificial tears and eye ointment. All patients are then followed up for a period of one year to assess the effects of the treatment.

What are the possible benefits and risks of participating?
Participation in the study is voluntary and no risk is associated with it. Patients can refuse to participate or withdraw at any time without it affecting their treatment. All information obtained for this study is used for research purposes only and will be kept strictly confidential.

Where is the study run from?
Dr. R.P. Centre for Ophthalmic Sciences, New Delhi (India)

When is the study starting and how long is it expected to run for?
December 2007 to November 2010

Who is funding the study?
Indian Council of Medical Research

Who is the main contact?
Professor Namrata Sharma

Contact information

Type(s)
Scientific

Contact name
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110029

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of topical Cyclosporin A drops in control of ocular inflammation in acute Stevens Johnson Syndrome

Study objectives
The aim of this study is evaluate the use of topical cyclosporine A drops in control of acute inflammation in acute Stevens Johnson Syndrome (SJS). This includes comparison of the following:

1. Assessment of ocular surface status
2. Improvement in tear film status
3. Corneal vascularization status

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee , All India Institute of Medical Sciences, 04/03/2007

Study design
A double blind randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Acute Stevens-Johnson Syndrome

Interventions
Participants are randomly allocated to one of two groups. Those in group 1 are treated with topical Cyclosporin A 1% drops along with the standard regime, followed from the day one of presentation. These patients are prescribed topical antibiotics, frequent lubrication in the form of artificial tears and lubricant eye ointment. Daily lysis of the symblepharon with copious irrigation with normal saline to wash of all the debris is also done.

Participants in group 2 are treated only with topical antibiotics and frequent lubrication with artificial tears drops and lubricant eye ointment.

Intervention Type

Primary outcome measure
1. Degree of inflammation, assessed using grading score for inflammation (conjunctival hyperaemia)
2. Degree of corneal vascularisation, assessed using grading score for corneal vascularisation

Measured pre-treatment and post treatment.

Secondary outcome measures
1. Any improvement in tear secretions, assessed using schirmer’s test
2. Ocular surface status, assessed using overall grading for ocular surface parameters

Measured pre-treatment and post treatment.

Overall study start date
01/12/2007

Completion date
30/11/2010

Eligibility

Key inclusion criteria
Patients of acute Stevens Johnson Syndrome

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
30 patients in case group, 30 patients in control group

Key exclusion criteria
1. Pregnant females
2. Lactating females
3. Children below 2 years
4. Patients who refuse consent
5. Patients with known sensitivity to cyclosporin
6. Patients with cardiac, renal and hepatic failure

Date of first enrolment
02/12/2007

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
India

Study participating centre
Dr.R.P.Centre for Ophthalmic Sciences
All India Institute of Medical Sciences
Ansari Nagar
New Delhi
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110029

Sponsor information

Organisation
All India Institute of Medical Sciences

Sponsor details
Ansari Nagar
New Delhi
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110029

Sponsor type
Government

Website
http://www.aiims.edu/en.html

ROR
https://ror.org/02dwcqs71

Funder(s)

Funder type
Government

Funder Name
Indian Council of Medical Research

Alternative Name(s)
Indian Council of Medical Research, Government of India, Indian Council of Medical Research (ICMR), New Delhi, ICMROrganisation, , Indian Council of Medical Research, New Delhi, ICMR, ICMRDELHI, ...

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
India

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
30/11/2011

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request