

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

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| Submission date 13/05/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 03/10/2016 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 03/10/2016 | Condition category Skin and Connective Tissue Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> 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 damage 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

Prof Namrata Sharma

Contact details

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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
India
110029

Sponsor information

Organisation

All India Institute of Medical Sciences

Sponsor details

Ansari Nagar
New Delhi
India
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