

Doxycycline and dexamethasone as effective topical treatments for blepharitis

Submission date 15/12/2008	Recruitment status Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/12/2008	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 02/10/2014	Condition category Eye Diseases	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Doxycycline and dexamethasone as effective topical treatments for blepharitis: a phase IV open randomised controlled therapeutic equivalence trial

Study objectives

Comparison between oral doxycycline and topical dexamethasone versus topical doxycycline and dexamethasone for the treatment of blepharitis.

On 19/03/2009 the following changes were made to the trial record:

1. The target number of participants was changed from 100 to 10 to 25 participants.
2. The sources of funding field was updated from 'Brudy Technology (Spain) - covering treatment costs' to 'Investigator-funded (Spain)'.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Phase IV open randomised controlled therapeutic equivalence trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Blepharitis

Interventions

Current interventions as of 19/03/2009:

Group 1: topical doxycycline 0.05% and topical dexamethasone 0.05% (the two drugs mixed into a single ointment) to be applied four times a day for four days, three times a day for four days, twice a day for four days and finally once a day for four days

Group 2: oral doxycycline 100 mg twice a day for 16 days, and topical dexamethasone 0.05% to be applied four times a day for four days, three times a day for four days, twice a day for four days and once a day for four days

Previous interventions:

Group 1: topical doxycycline 0.05% and topical dexamethasone 0.05% (the two drugs mixed into a single ointment) to be applied three times a day during week 1, twice a day during week 2, and once a day during week 3

Group 2: oral doxycycline 100 mg twice/day for 14 days, then 100 mg once a day for 7 days and topical dexamethasone 0.05% to be applied three times a day during week 1, twice a day during week 2, and once a day during week 3.

Updated 30/04/2014: the trial was stopped due to lack of funding.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Doxycycline, dexamethasone

Primary outcome(s)

Symptoms assessed with a questionnaire (with a numerical scale): improvement of comfort, assessed before first treatment (baseline) and between 1 and 7 days after the end of treatment.

Key secondary outcome(s)

1. Presence or absence of conjunctival infection before and after treatment
2. Safety of topical doxycycline compared with oral doxycycline

Duration of follow-up: 16 days (updated 19/03/2009; previously 20 days)

Completion date

01/05/2009

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

1. Both males and females, aged older than 18 years
2. No other topical treatments
3. Diagnosis of blepharitis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not meet the inclusion criteria

Date of first enrolment

01/02/2009

Date of final enrolment

01/05/2009

Locations

Countries of recruitment

Spain

Study participating centre

Hospital Publico de Hospitales del Alto Guadalquivir

Córdoba

Spain

CP 14500

Sponsor information

Organisation

Puente Genil Hospital (Hospital de Alta Resolución de Puente Genil) (Spain)

Funder(s)

Funder type

Other

Funder Name

Investigator-funded (Spain)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration