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Doxycycline and dexamethasone as effective topical treatments for blepharitis

Submission date 15/12/2008	**Recruitment status** Stopped	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 23/12/2008	**Overall study status** Stopped	
Last Edited 02/10/2014	**Condition category** Eye Diseases	

Plain English Summary
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 hypothesis
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

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 below to request a patient information sheet

Condition
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 measure
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.

Secondary outcome measures
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)

Overall study start date
01/02/2009

Overall study end date
01/05/2009

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Participant 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
10 to 25 participants

Participant exclusion criteria
Does not meet the inclusion criteria

Recruitment start date
01/02/2009

Recruitment end date
01/05/2009

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Publico de Hospitales del Alto Guadalquivir
Córdoba
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CP 14500

Sponsor information

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

Sponsor details
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Other

Funder Name
Investigator-funded (Spain)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration