

# Doxycycline and dexamethasone as effective topical treatments for blepharitis

<b>Submission date</b> 15/12/2008	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/12/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/10/2014	<b>Condition category</b> 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

**Contact name**  
Dr Enrique Villegas Becerril

**Contact details**  
Hospital Publico de Hospitales del Alto Guadalquivir  
C/ Miguel Quintero Merino s/n  
Polígono Industrial Las Acacias  
Puente Genil  
Córdoba  
Spain  
CP 14500  
+34 (0) 957 61 50 00  
evillegas@ephag.es

## Additional identifiers

## 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