Study of COLAL-PRED® in the treatment of moderate acute ulcerative colitis

Submission date	Recruitment status	Prospectively registered
10/03/2006	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
29/03/2006	Completed	Results
Last Edited	Condition category	[] Individual participant data
31/01/2019	Digestive System	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

University Hospital Nottingham United Kingdom NG7 2UH

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00299013

Secondary identifying numbers ATL2502/020/CL

Study information

Scientific Title

Study of COLAL-PRED® in the treatment of moderate acute ulcerative colitis

Study objectives

The aim of this study is to investigate whether COLAL-PRED® is non-inferior in terms of efficacy and superior in terms of safety to that of conventional prednisolone in the treatment of moderate acute ulcerative colitis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Southampton and South West Hampshire Research Ethics Committees (A), 11/10/2005, ref: 05/Q1702/128

Study design

Randomised double-blind double-dummy active-comparator parallel-group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Moderate acute ulcerative colitis

Interventions

Patients are randomised to receive one of the following interventions:

- 1. Capsules containing prednisolone metasulfobenzoate sodium in a colonic delivery system
- 2. Prednisolone tablets
- 3. Matching placebo capsules and tablets

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

COLAL-PRED® containing prednisolone metasulfobenzoate sodium

Primary outcome measure

- 1. Responder analysis for reduction in disease activity index (DAI) score
- 2. Responder analysis for safety based on morning cortisol levels

Secondary outcome measures

Treatment responder analysis of patients who are both efficacy and safety responders

Overall study start date

07/03/2006

Completion date

31/03/2007

Eligibility

Key inclusion criteria

- 1. Endoscopically confirmed diagnosis of ulcerative colitis
- 2. Score of 6-10 on the disease activity index (DAI)
- 3. Moderate to severe mucosal appearance

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

750

Key exclusion criteria

- 1. Previous colonic surgery
- 2. Other treatments for ulcerative colitis that have not been stabilised
- 3. Clinically significant diabetes
- 4. Heart failure
- 5. Unstable angina
- 6. Cirrhosis
- 7. Renal failure
- 8. History of tuberculosis

Date of first enrolment

07/03/2006

Date of final enrolment

31/03/2007

Locations

Belgium Czech Republic Denmark England France Germany Hungary Israel Italy Poland Russian Federation South Africa Spain Sweden **United Kingdom**

Countries of recruitment

Australia

Study participating centre University Hospital Nottingham United Kingdom NG7 2UH

Sponsor information

Organisation

Alizyme (UK)

Sponsor details

Granta Park Great Abington Cambridge United Kingdom CB1 6GX +44 (0)1223 896 000 Medical.Information@alizyme.co.uk

Sponsor type

Industry

Website

http://www.alizyme.com

Funder(s)

Funder type

Industry

Funder Name

Alizyme (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Company presentation of results in http://ww7.investorrelations.co.uk/alizyme/uploads/reports/0724COLAL-PREDresultsFINAL.pdf

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration