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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

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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

Countries of recruitment
Australia

Belgium

Czech Republic

Denmark

England

France

Germany

Hungary

Israel

Italy

Poland

Russian Federation

South Africa

Spain

Sweden

United Kingdom

Study participating centre
University Hospital
Nottingham
United Kingdom
NG7 2UH

Sponsor information

Organisation
Alizyme (UK)

Sponsor details
Granta Park
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CB1 6GX
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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