

A double-blind comparative study of Predocol 40 and 60 mg per day and prednisolone 40 mg per day, comparing clinical efficacy, safety and adrenal function in the treatment of acute exacerbations of ulcerative colitis

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Registration date 08/11/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/02/2017	Condition category Digestive System	<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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Predocol 2001

Study information

Scientific Title

A double-blind comparative study of Predocol 40 and 60 mg per day and prednisolone 40 mg per day, comparing clinical efficacy, safety and adrenal function in the treatment of acute exacerbations of ulcerative colitis

Acronym

PIAF

Study objectives

The primary objectives of the study are to compare the clinical efficacy and safety of treatment with either orally administered prednisolone Metasulfobenzoate (MSB) (Predocol) or standard oral prednisolone in patients with acute exacerbations of ulcerative colitis. Treatment will be administered for eight weeks, and adrenal function will be measured before and after the treatment period by the synacthen test.

Please note that this study provides additional efficacy data to another study entitled: 'A safety and efficacy study of a novel formulation of prednisolone metasulfobenzoate (Predocol) in the induction of remission and maintenance in patients with ulcerative colitis' [ISRCTN14133410] and, in particular, focuses on adrenal safety.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridge Local Research Ethics Committee (LREC) on 27/06/2000.

Further approval was received from Eastern Region Multi-Centre Research Ethics Committee (MREC) on the 29/01/2003 (ref: 02/5/58)

Study design

The study is a double-blind randomised study in patients with ulcerative colitis randomised to one of three treatment groups.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Acute exacerbations of ulcerative colitis

Interventions

Three treatment groups:

Group A: 40 mg Predocol per day in divided doses for eight weeks

Group B: 60 mg Predocol per day in divided doses for eight weeks

Group C: 40 mg enteric coated prednisolone each day in divided doses, reducing to zero over eight weeks. Dummy capsules will be used to maintain blinding

Safety follow-up for all groups is for 3 - 7 days post final visit at week 8.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Prednisolone Metasulfobenzoate (MSB) (Predocol), prednisolone

Primary outcome measure

1. Efficacy, measured using the Powell-Tuck score, assessed during and up to week 8 of treatment (final visit at week 8)
2. Safety, measured using levels of cortisol 30 minutes and one hour after synacthen injection on the last visit of the study, 3 to 7 days after the patient has completed eight weeks of treatment with study drug. Changes in cortisol levels from the screening synacthen test will also be analysed

Secondary outcome measures

1. Efficacy, measured using the physician's clinical grading and the physician's global assessment, assessed during and up to week 8 of treatment (final visit at week 8).
2. Safety, including reported adverse events and major changes in laboratory data, and findings of potential clinical concern, measured during and up to 3 - 7 days after final visit at end of week 8 of treatment

Overall study start date

18/05/2001

Completion date

29/11/2006

Eligibility

Key inclusion criteria

To be enrolled in the study patients are required to meet the following inclusion criteria:

1. Histologically confirmed ulcerative colitis, considered suitable for therapeutic treatment with Predocol or prednisolone

2. Active inflammation of the bowel categorised as mild, moderate or severe
3. At least 18 years old
4. Given written informed consent to participate

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120 patients meeting eligibility requirements

Key exclusion criteria

Patients are excluded from the study if any of the following applies:

1. Have taken more than three doses of steroids within the past month before entry into the study
2. Pregnant and nursing mothers
3. Significant renal, hepatic, cardiovascular or neuropsychiatric impairment, diabetes, Acquired Immune Deficiency Syndrome (AIDS) (or Human Immunodeficiency Virus [HIV]) or other chronic infections, osteoporosis, a transplanted organ, malignancy, lymphoproliferative disease, or substance abuse
4. Have had opportunistic or serious infections, such as hepatitis, pneumonia, or pyelonephritis in the previous three months
5. Require the concomitant use of drugs likely to suppress daytime gastric acidity (omeprazole or large doses of H2 antagonist drugs)
6. Known to have Crohn's disease
7. Considered by their physician unlikely to be able to comply with the protocol
8. Very severe colitis evidenced by toxic dilatation or for whom admission or surgery seems imminent
9. Female patients of child bearing potential. Such patients must use a reliable form of contraception throughout the period of the study to be eligible for the study
10. Have taken part in an experimental drug study in the preceding three months

Date of first enrolment

18/05/2001

Date of final enrolment

29/11/2006

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre
Department of Gastroenterology
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Flexpharm Ltd (UK)

Sponsor details
Elite House
Hill Farm Industrial Estate
Leavesden
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United Kingdom
WD25 7SA

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Enterotech Ltd (Jersey)

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