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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

Submission date 11/10/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 08/11/2007	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 14/02/2017	**Condition category** Digestive System	[ ] Individual participant data [ ] 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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

England

Study participating centre
Department of Gastroenterology
Cambridge
United Kingdom
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Sponsor information

Organisation
Flexpharm Ltd (UK)

Funder(s)

Funder type
Industry

Funder Name
Enterotech Ltd (Jersey)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration