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Efficacy of mesalazine to prevent relapse in paediatric crohns disease

Submission date	Recruitment status	[ ] Prospectively registered
13/02/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
10/03/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
10/03/2008	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

Secondary identifying numbers
Etude Pentacomp/90/91

Study information

Scientific Title
Prevention of relapse by mesalazine (Pentasa®) in paediatric crohn's disease: a multicentric double-blind randomised placebo-controlled trial

Study objectives
The trials primary objective was to compare the efficacy of mesalazine (Pentasa®, Ferring) versus placebo in maintaining remission in paediatric crohn's disease (CD) patients, when used after the successful treatment of an acute episode with either medication alone or parenteral /enteral nutrition techniques combined or not with medication.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethcis approval received from the Ethics Committee of Paris VII on the 10th January 1991 (ref: Etude Pentacomp/90/01).

Study design
A multicentric, double-blind, randomised, placebo-controlled trial

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
Paediatric crohn's disease

Interventions
At inclusion, patients were randomised per stratum, within each centre, using random permuted two to four sized-blocks (each centre did not know the size of their own block), to the following:
1. 50 mg/kg/day mesalazine dose
2. Placebo (identical tablets)

This was taken over a one-year period. Patients were monitored every three months over a one-year period or until endpoint.

The study treatment was initiated either one week after the interruption of parenteral or enteral nutrition, or at the end of a sulfalazine or metronidazole treatment, or if the prednisone dose during the steroid weaning period was below 0.2 mg/kg. After the study treatment began, only antispasmodic and antidiarrhoeal agents, as well as sedatives were to be given as possible additional medications.

Following the recruitment of 57 children from 1991 to 1993, trial results showed a trend favouring mesalazine. Recruitment was consequently resumed from 1996 to 1999.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mesalazine (Pentasa®)

Primary outcome measure
1. Clinical relapse (HB score greater than or equal to 5, if confirmed within two weeks)
2. Surgery for an acute complication of CD

Primary and secondary outcomes were measured either at one year of follow up with a medical visit every three months or when the primary or secondary outcomes occur during the one year follow up.

Secondary outcome measures
Treatment failure, defined as:
1. Relapse
2. Failure of steroid withdrawal (weaning failure)
3. Side-effects intolerance requiring treatment discontinuation
4. Worsening or aggravation of patient status requiring treatment interruption
5. Initiation of a new treatment as decided by the clinician

Primary and secondary outcomes were measured either at one year of follow up with a medical visit every three months or when the primary or secondary outcomes occur during the one year follow up.

Overall study start date
01/01/1991

Completion date
01/01/1998

Eligibility

Key inclusion criteria
1. Children less than 18 years old, either sex
2. Diagnosed with crohns disease before the age of 16 by means of clinical, radiological, endoscopic and histological data
3. Had to be in an active phase defined by:
3.1. A Harvey Bradshaw score (HB) greater than or equal to 5, and
3.2. An erythrocyte sedimentation rate (ESR) greater than or equal to 25 mm at hour one
4. All lesion localisations, except exclusive anorectal localisation, were included, providing patients lesion extension had been assessed within two years prior to inclusion

After flare-up treatment, inclusion criteria were as follows:
1. Patients in clinical remission within six months following flare-up treatment initiation at pre-inclusion
2. An HB score under 5
3. An ESR under 25 mm
4. Normal hepatic and renal functions

Participant type(s)
Patient

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
60, extended to 120

Key exclusion criteria
1. Flare-up had been treated with mesalazine or had required immuno-suppressors
2. Patients with known hypersensitivity to salicylate
3. Patients whose flare-up had occurred at pre-inclusion when on a 5-aminosalicylic acid (5-ASA) dose greater than 50 mg/kg/day for over two months

Date of first enrolment
01/01/1991

Date of final enrolment
01/01/1998

Locations

Countries of recruitment
France

Switzerland

Study participating centre
Hopital Robert Debré 48 Bd Sérurier
Paris
France
75019

Sponsor information

Organisation
Ferring SA (France)

Sponsor details
7 rue Jean Baptiste Clément
Gentilly
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94250

Sponsor type
Industry

ROR
https://ror.org/03vrwsp35

Funder(s)

Funder type
Industry

Funder Name
Ferring SA (France)

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