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A multicenter, randomized, double-blind, placebo-controlled investigation of long-term safety and efficacy of LCAP (leukocytapheresis using "Cellsorba FX") in patients with refractory, chronic active ulcerative colitis

Submission date 28/10/2004	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/01/2005	**Overall study status** Stopped	
Last Edited 13/12/2007	**Condition category** Digestive System	

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
1.6 - 07/2004

Study information

Scientific Title

Acronym
MICELL-UC

Study objectives
Study hypothesis added as of 8 June 2007: Assessment of long-term safety and efficacy of leukocytapheresis with Cellsorba FX in comparison to sham-leukocytapheresis for patients with refractory, chronic active ulcerative colitis (CAI 6-10).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval information added as of 8 June 2007:

Approvals of the following ethics committees were obtained on 19 August 2004:
1. Hannover Medical School (MHH)
2. University (LMU) of Munich
3. University of Erlangen
4. Medical association of Mecklenburg-Western Pomerania (Rostock)
5. University of Munster
6. Charité, University of Berlin
7. Medical association of Rhineland-Palatinate (Mainz)

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Refractory, chronic active ulcerative colitis

Interventions
Please note that this study was terminated on 25 April 2007 due to unsatisfactory patient enrolment.

Interventions provided at registration:
Extracorporeal leukocytapheresis (LCAP; verum group) versus sham-leukocytaphersis (placebo group)

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Primary outcome measures added as of 8 June 2007:

The primary efficacy parameter is the 7-item Clinical Activity Index (CAI). A sum score will be calculated summing up all items that are differently weighted. The range of the sum score is 0 to 29 points. A sum score of less than four (or less than or equal to 4) points at the end of the therapy will be assessed as remission or success.

Key secondary outcome(s))
Secondary outcome measures added as of 8 June 2007:

1. Inflammatory Bowel Disease Questionnaire (IBDQ), German translation. This questionnaire consists of four domains and 32 items. Domains are simply the sum of specific items, i.e. bowel symptoms, systemic symptoms, emotional functions and social functions.
2. Endoscopic Index (EI), which includes 4 items with different weights. The range of the sum score is 0 to 12 points.
3. Cumulative steroid dose over intensive and maintenance phase.
4. CAI, item-wise analysis.

Completion date
31/12/2006

Reason abandoned (if study stopped)
The trial will be terminated due to unsatisfactory patient enrolment: during the scheduled period of 24 months, less than 50% of patient enrolment has been completed.

Eligibility

Key inclusion criteria
1. Ulcerative colitis with chronic active disease state
2. Colitis endoscopically covering at least 15 cm
3. Clinical Activity Index: 6-10
4. No long term remission using combined standard therapy including 5-Aminosalicylate (ASA), prednisolone and/or azathioprine
5. Cumulative steroid dosage within the last 2 months in total at least 600 mg
6. Steroid dosage constant 10 mg per day during 2 weeks before start of treatment (pre-treatment phase)
7. Negative test of pregnancy for female patients
8. Patient is able to understand and sign informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Not Specified

Sex
All

Key exclusion criteria
Exclusion criteria added as of 8 June 2007:
1. Age < 18 or ≥ 80 years
2. Effective response to conventional Ulcerative Colitis (UC) therapy
3. Diagnosis of proctitis or mild UC (usually controlled by aminosalicylates and suppository steroid therapies)
4. Active symptoms which would exclude the patient from undergoing routine diagnostic colonoscopy i.e. evidence of active bowel obstruction, intestinal perforation, significant GI hemorrhage or known high-grade stricture
5. Body weight is less than 40 kg
6. Any malignant disease currently or in history
7. Renal failure and/ or hepatic failure (Glutamate Oxalate Transferase [GOT], Glutamic-Pyruvic Transaminase [GPT], total billirubin, creatinine > twice the normal value)
8. Chronic hypotension (80 mmHg or lower systolic)
9. Therapeutic anticoagulation (Cumarine) or coagulation disorder
10. Active bacterial or viral infection, especially acute or chronic Hepatitis B or C virus infection, or HIV infection
11. Severe cardiovascular disease (New York Heart Association [NYHA] III-IV or Canadian Cardiovascular Society [CCS] III-IV), which would not permit any extracorporeal treatment
12. Breast feeding, pregnancy, drug abuse or dementia
13. Participation in another clinical study in the last 3 months

Date of first enrolment
01/11/2004

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Germany

Study participating centre
Apheresis Research Institute
Cologne
Germany
50935

Sponsor information

Organisation
Asahi Kasei Medical Europe GmbH (Germany)

ROR
https://ror.org/040cmp171

Funder(s)

Funder type
Industry

Funder Name
Source of funding added as of 8 June 2007:

Funder Name
Asahi Kasei Medical Europe GmbH, Lyoner Strasse 44-48, 60528 Frankfurt (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration