Clinical trial registration statement

Ref.: ADAPT study
internal CIP ID: Ada-UC-08-101
ClinicalTrial.gov number: NCT 00781638

The ADAPT study is registered at ClinicalTrials.gov.

URL: https://www.clinicaltrials.gov/ct2/show/NCT00781638?term=adacolumn&rank=2

The registration identification number is NCT00781638.

i.A. R. 01 DEC 2015

Dr. med. Raphael Gruber
Clinical and Medical Director – Medical Devices, Europe
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→ Trial registration

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ADAPT Adacolumn Pediatric Trial in Ulcerative Colitis

This study has been completed.

Sponsor:
Otsuka Frankfurt Research Institute GmbH

Information provided by (Responsible Party):
Otsuka Frankfurt Research Institute GmbH

ClinicalTrials.gov Identifier:
NCT00781638

First received: October 28, 2008
Last updated: April 2, 2012
Last verified: April 2012
History of Changes

Full Text View | Tabular View | No Study Results Posted | Disclaimer | How to Read a Study Record

Tracking Information

First Received Date ICMJE	October 28, 2008
Last Updated Date	April 2, 2012
Start Date ICMJE	October 2008
Primary Completion Date	March 2012 (final data collection date for primary outcome measure)
Current Primary Outcome Measures ICMJE **(submitted: October 28, 2008)**	Primary response variable: Changes in mean PUCAI between baseline and Week 12 [Time Frame: 12 Weeks plus 1 year Follow up] [Designated as safety issue: No]
Original Primary Outcome Measures ICMJE	*Same as current*
Change History	Complete list of historical versions of study NCT00781638 on ClinicalTrials.gov Archive Site
Current Secondary Outcome Measures ICMJE **(submitted: October 28, 2008)**	Difference in Endoscopic Activity Index (EAI) according to Rachmilewitz between Week 12 and baseline for those patients with 2 endoscopies [Time Frame: Week 12] [Designated as safety issue: No]
Original Secondary Outcome Measures ICMJE	*Same as current*
Current Other Outcome Measures ICMJE	*Not Provided*
Original Other Outcome Measures ICMJE	*Not Provided*

Descriptive Information

Brief Title ICMJE	ADAPT **Adacolumn** Pediatric Trial in Ulcerative Colitis
Official Title ICMJE	Open Uncontrolled Investigation to Assess the Efficacy and Safety of **Adacolumn®** Granulocytes, Monocytes / Macrophage Apheresis Device in Children and Adolescents With Active Ulcerative Colitis
Brief Summary	Children aged up to 18 years with moderately active Ulcerative Colitis (PUCAI:35-64) will receive one weekly **Adacolumn®** apheresis treatment over 5 consecutive weeks, followed by up to 3 optional **Adacolumn®** apheresis treatments over 3 consecutive weeks. Primary end point is PUCAI at Week 12. The main part of the clinical investigation will be continued by a one year follow up for responders.

Detailed Description	The individual clinical investigation period will be 12 weeks per patient. If the patient will take part in the follow up, the individual clinical investigation period will be 64 weeks. Patients receive one weekly Adacolumn® apheresis over 5 consecutive weeks. The treating investigator may decide to add up to 3 treatments based on his judgment. Treatment details Day -07: Screening; Day 00 Baseline: 1st Adacolumn® apheresis; Day 07: 2nd Adacolumn® apheresis; Day 14: 3rd Adacolumn® apheresis; Day 21: 4th Adacolumn® apheresis; Day 28: 5th Adacolumn® apheresis; Week 12:Final evaluation
Study Type ICMJE	Interventional
Study Phase	*Not Provided*
Study Design ICMJE	Allocation: Non-Randomized Intervention Model: Single Group Assignment Masking: Open Label Primary Purpose: Treatment
Condition ICMJE	Ulcerative Colitis
Intervention ICMJE	Device: **Adacolumn®** The medical device **Adacolumn®** (CE-Mark Certificate G1 07 01 366 76013) is an adsorptive type extracorporeal apheresis column. It has been shown to effectively improve clinical and endoscopic signs and symptoms in UC in adults by removing granulocytes and monocytes and by changing the Cytokine production. Other Name: GMA apheresis (Granulocytes/Monocytes adsorptive apheresis).
Study Arm (s)	*Not Provided*
Publications *	*Not Provided*

*** Includes publications given by the data provider as well as publications identified by ClinicalTrials.gov Identifier (NCT Number) in Medline.**

Recruitment Information

Recruitment Status ICMJE	Completed
Enrollment ICMJE	24
Completion Date	March 2012
Primary Completion Date	March 2012 (final data collection date for primary outcome measure)
Eligibility Criteria ICMJE	Inclusion Criteria: 1. Children and adolescents < 18 years 2. Ulcerative colitis documented by clinical symptoms, endoscopic findings and histology (in patient history) 3. Moderate active ulcerative colitis at baseline evaluation, defined as follows:PUCAI between 35 and 64 4. Pancolitis or left-sided colitis 5. Ulcerative colitis for at least 3 months 6. Receiving or having received one or more of the following medicinal products before screening: ◦ Sulfasalazine, mesalamine and other 5-aminosalicylic acid (5-ASA) agents for 4 weeks or more with a stable dose for the last 2 weeks, ◦ 0.5mg/kg/body weight with a maximum of 20 mg per day of prednisone with a stable dose for the last 2 weeks, or ◦ 6-mercaptopurine or azathioprine for 12 weeks or more with a stable dose for the last 4 weeks Other UC medication is not allowed (see also Chapter 4.4.2). 7. For female patients of child-bearing potential, a negative pregnancy test and agreement to use an effective contraceptive method or abstain from sexual activities during the course of the clinical investigation 8. Agreement to participate in all visits 9. Signed written informed consent document by patients and their legal guardian or representative 10. Body weight must be more or equal 30kg

11. Adequate peripheral venous access to allow for completion of the apheresis treatments

Exclusion Criteria:

1. Febrile (>38°C)
2. Evidence of toxic megacolon
3. Anticipated need for surgery within 12 weeks after Day 00
4. Major surgery within the past 6 weeks
5. Known obstructive diseases of the gastrointestinal system
6. Proctocolectomy, total colectomy, ileostomy, stoma or ileal pouch-anal anastomosis
7. A history of allergic reaction to heparin or heparin-induced thrombocytopenia
8. A history of hypersensitivity reaction associated with an apheresis procedure or intolerance of apheresis procedures
9. Known infection with enteric pathogens, pathogenic ova or parasites, or a positive assay for C. difficile toxin
10. Symptomatic hypotension
11. Pediatric heart conditions and problems at high susceptibility for thrombotic events (e.g. valve defects or similar)
12. A history of physical findings compatible with a cerebrovascular accident
13. Prosthetic heart valve, pacemaker or other permanent implant
14. Severe cardiovascular or peripheral vascular disease
15. Liver disease defined as levels of GOT [AST], GPT [ALT] or alkaline phosphatase >2.5x the upper limit of the normal range for the laboratory performing test
16. History of cirrhosis
17. Renal insufficiency, defined as serum creatinine >150% of the upper limit of the normal range for the laboratory performing the test
18. Known bleeding disorder (PT or PTT>1.5x the upper limit of the normal range for the laboratory performing the test), or concomitant anticoagulant therapy for purposes other than apheresis treatment
19. Prior history suggestive of a hypercoagulable disorder, including 1 or more episodes of pulmonary embolism or deep vein thrombosis
20. Known infection with Hepatitis B or C, or HIV
21. Abnormal hematology parameters defined as severe anemia with hemoglobin <8.5g/dL, white blood cell count of <3,500/µl and a granulocyte count <2,000/µl
22. Fibrinogen level >700mg/dL
23. Infection:
    - Active infections from successful completion of antibiotic treatment for routine bacterial infection less than 4 weeks of entry into the clinical investigation (screening)
    - Febrile viral infection within 4 weeks of entry into the clinical investigation (screening)
    - Less than 12 weeks from conclusion of therapy for systemic fungal infections to screening
24. Malignancy within the past 2 years other than surgically cured skin carcinoma or cervical dysplasia (CIN I-II)
25. History of dysplasia or carcinoma of the colon
26. Current drug or alcohol abuse
27. Pregnant, lactating or planning to become pregnant during the course of the clinical investigation
28. Used within the last 30 days an investigational medicinal product, biologic or device
29. Pre-treatment of UC with drugs other than 5-ASA and derivatives, azathioprine and or corticosteroids, e.g. immunosuppressants and biologics
30. Steroid-resistance or -dependency, defined as inability to completely withdraw steroids without inducing a relapse or flare-up of the disease
31. Topical therapy for ulcerative colitis within the last 2 weeks.

Gender	Both
Ages	up to 18 Years
Accepts Healthy Volunteers	No
Contacts ICMJE	*Contact information is only displayed when the study is recruiting subjects*
Listed Location Countries ICMJE	*Not Provided*

Removed Location Countries	Finland

Administrative Information

NCT Number [ICMJE]	NCT00781638
Other Study ID Numbers [ICMJE]	Ada-UC-08-101
Has Data Monitoring Committee	No
Responsible Party	Otsuka Frankfurt Research Institute GmbH
Study Sponsor [ICMJE]	Otsuka Frankfurt Research Institute GmbH
Collaborators [ICMJE]	*Not Provided*
Investigators [ICMJE]	Principal Investigator: Tarja Ruuska, MD, PhD Tampere University Hospital
Information Provided By	Otsuka Frankfurt Research Institute GmbH
Verification Date	April 2012

[ICMJE] **Data element required by the International Committee of Medical Journal Editors and the World Health Organization ICTRP**

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R. Gruber

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