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- Trial identification
- Workflow information
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- Information on the IMP/placebo
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Ergebnisberichte
(nicht vorhanden)

4/3 von 3 BfArM: Datenbank Clinical Trials (PCT00) © BMG

2007-007928-18 Evaluation of efficacy and safety of the herbal drug Myrrhinil-Intest vs. mesalazine in maintaining clinical remission of ulcerative colitis - a 12-month, multicenter, randomized, prospective, double-blind, double-dummy, active-controlled and parallel group phase IV-trial

Entry in CT-Database (OFF):

Trial identification

EudraCT number:	2007-007928-18
Full title of the trial:	Evaluation of efficacy and safety of the herbal drug Myrrhinil-Intest vs. mesalazine in maintaining clinical remission of ulcerative colitis - a 12-month, multicenter, randomized, prospective, double-blind, double-dummy, active-controlled and parallel group phase IV-trial
Abbreviated title:	MIRCU
Sponsor's protocol code number:	Repha_1328
Trial part of a PIP:	Not answered

Workflow information of National Competent Authority

Zuständige Behörde:	BfArM
Bescheiddatum Bundesoberbehörde:	20080604
Bescheidart Bundesoberbehörde:	Genehmigung
Bescheiddatum Ethikkommission:	20080506
Bescheidart Ethikkommission:	positiv
Stand der Studie/Art:	Beendigung
Datum/Ende der Studie in Deutschland:	20100831

Sponsor identification

Sponsor

Status of the Sponsor: Commercial

REPHA GmbH
Germany

Information on the investigational medicinal product(s)/placebo(s)

1: (PR1)

Product role: Test

IMP - Status of the investigational medicinal product

IMP has a marketing authorisation:	Y
Trade name:	Myrrhinil-Intest®
Name of marketing authorisation holder:	Repha GmbH
Marketing authorisation granted by:	Germany

IMP - Description of the investigational medicinal product

Pharmaceutical form:	Coated tablet
Specific paediatric formulation:	Not answered
Route of administration:	Oral use

Active substance-INN / proposed INN:	MATRICARIA FLOWER
Active substance - other descriptive name:	MATRICARIA FLOWER

Concentration type:	exact number
Concentration number part 1:	70
Concentration unit:	mg milligram(s)

Active substance-INN / proposed INN:	MYRRH
Active substance - CAS number:	9000457
Active substance - other descriptive name:	MYRRH
Concentration type:	exact number
Concentration number part 1:	100
Concentration unit:	mg milligram(s)

Active substance-INN / proposed INN:	COFFEE COAL
Active substance - CAS number:	8000047907
Active substance - other descriptive name:	COFFEE COAL
Concentration type:	exact number
Concentration number part 1:	50
Concentration unit:	mg milligram(s)

IMP - Type of the IMP

Acitve substance origin - biological / biotechnological:	Y
Medicinal product type - herbal:	Y

IMP - Regulatory information

Orphan drug designation in the Community:	N

2: (PR2)

Product role:	Comparator

IMP - Status of the investigational medicinal product

IMP has a marketing authorisation:	Y
Trade name:	Salofalk® 500mg
Name of marketing authorisation holder:	Dr. Falk Pharma GmbH
Marketing authorisation granted by:	Germany

IMP - Description of the investigational medicinal product

Pharmaceutical form:	Gastro-resistant tablet
Specific paediatric formulation:	Not answered
Route of administration:	Oral use

Active substance-INN / proposed INN:	MESALAZINE
Active substance - CAS number:	89576
Concentration type:	exact number
Concentration number part 1:	500
Concentration unit:	mg milligram(s)

IMP - Type of the IMP

Active substance origin - chemical:	Y

IMP - Regulatory information

Orphan drug designation in the Community:	N

Placebo - Information on the placebo(s)

Placebo in this trial:	Y

1: (PL1)

Placebo - pharmaceutical form:	Coated tablet
Placebo - route of administration:	Oral use

2: (PL2)

Placebo - pharmaceutical form:	Gastro-resistant tablet
Placebo - route of administration:	Oral use

Information on the trial

General information on the trial

Medical condition: ulcerative colitis patients in clinical remission

MedDRA:	MedDRA version code	MedDRA level	MedDRA classification code	MedDRA term
	9.1	LLT	10045365	Ulcerative colitis

Rare disease: N

Main objective of the trial: The main objective of the trial is to confirm Myrrhinil-Intest's non-inferiority versus mesalazine concerning the activity of ulcerative colitis in remission over the treatment period.

Secondary objectives of trial: Efficacy parameters: Duration until relapse; general condition assessment by the physician and patient; social activity of the patient; constitution of the patient; efficacy assessment by the physician; quality of life; inflammatory parameters: lactoferrine, pmn elastase and calprotectin; mucosal healing; histologic healingSafety parameters: adverse events; blood count: CRP, leukocytes, thrombocytes, Hb, serum creatinine, AST and ALT, blood sedimentation rate; vital signs; tolerance of the investigational product; occurrence of relapses in patients; relapse rate

Sub-study: Y

Sub-study details: Title: Investigation of predictive factors for relapse and non-invasive fecal markers in monitoring of patients with ulcerative colitis - a prospective longitudinal study over 6 months Date: 16-06-2008Version:1.0Objectives:The aim of the study is to investigate predictive factors for relapse and faecal parameters as non-invasive markers in monitoring of patients with ulcerative colitis. Furthermore it is to be determined if the extent of chronic stress, cell structures or genetic patterns differ

Principal inclusion criteria: -patients of both gender, >= 18 years of age-patients diagnosed with ulcerative colitis (clinical, endoscopic, histological) and in remission between 1 week and 1 year according to colitis activity index (CAI, defined by Rachmilewitz) <= 4 at enrollment-signed informed consent

Principal exclusion criteria: -use of steroids or antibiotics for ulcerative colitis together with the investigational procuct-intake of Escherichia coli Nissle and Psyllii semen together with the investigational product-administration of the following drugs within the previous 3 months before trial entry and during the trial: 'biologicals' (Infliximab, Mycophenolat, Tacrolimus, Thalidomid), other drugs to modify immune response (Methotrexat, Azathioprin) or/and drugs in clinical development -total parenteral nutrition, formula diet-infectious or chronic active ulcerative colitis-active ulcerative colitis at trial entry-condition after complete colectomy-malignant tumor disease within the last 5 years and/or malignant tumor disease older than 5 years which can not be considered cured according to the investigator's judgement (except superficial basal cell, squamous cell carcinoma, or basalioma of the skin which has been completely resected or can be considered cured) or/and clinical significant cardiac, hepatic or renal dysfunctions or diseases of the CNS, lung, immune system or gastro-intestinal diseases (in addition to ulcerative colitis)-known alcohol or drug abuse-known intolerance to the ingredients-pregnancy or in the physician's opinion unreliable contraception for women of childbearing years

Primary endpoints: The primary endpoint is the averaged colitis activity index (defined by Rachmilewitz) of a patient over the treatment period.

Trial scope

Scope - diagnosis: N
Scope - prophylaxis: N
Scope - therapy: Y
Scope - safety: Y
Scope - efficacy: Y
Scope - pharmacokinetic: N
Scope - pharmacodynamic: Y
Scope - bioequivalence: N
Scope - dose response: N
Scope - pharmacogenetic: N
Scope - pharmacogenomic: N
Scope - pharmacoeconomic: N
Scope - others: Y
Scope - others/specified: quality of life

Trial phase and type

Trial phase - Phase I: N

First administration to humans:	N
Bioequivalence study:	N
Other type of study:	N
Trial phase - Phase II:	N
Trial phase - Phase III:	N
Trial phase - Phase IV:	Y

Trial design

Trial design - controlled:	Y
Trial design - open:	N
Trial design - randomised:	Y
Trial design - single blind:	N
Trial design - double blind:	Y
Trial design - parallel group:	Y
Trial design - cross over:	N
Trial design - other:	N
Trial design - controlled/comparator other medicinal product:	Y
Trial design - controlled/comparator placebo:	N
Trial design - controlled/comparator other:	N
Single site in Member State:	N
Multiple sites in Member State:	Y
Number of sites anticipated in the Member State concerned:	2
Multiple Member States:	N
3rd Countries involved - trial conducted both within and outside EEA:	N
3rd Countries involved - trial conducted completely outside the EEA:	Not answered
Data monitoring committee in this trial:	Y
Initial estimate of trial duration in this Member State - years:	2

Population of trial subjects

Age span

Less than 18 years:	N
In utero:	Not answered
Preterm newborn infants (gestational age less than 37 weeks):	Not answered
Newborn (0 - 27 days):	Not answered
Infant and toddler (28 days - 23 months):	Not answered
Children (2 - 11 years):	Not answered
Adolescents (12 - 17 years):	Not answered
Adults (18 - 64 years):	Y
Elderly (>= 65 years):	Y

Gender

Gender - male:	Y
Gender - female:	Y

Group of trial subjects

Subject - healthy volunteers:	N
Subjects - patients:	Y
Subjects - specific vulnerable populations:	Y
Subjects - women of child-bearing potential not using contraceptives (s. Hinweis auf der Webseite):	N
Subjects - women of child-bearing potential using contraceptives:	Y
Subjects - pregnant women:	N
Subjects - nursing women:	N

Subjects - emergency situation:	N
Subjects incapable of giving consent personally:	N
Subjects - other types of subjects:	N

Planned number of trial subjects

Number of subjects in this Member State:	100

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