Clinical trial results:
Prevention of HBV reinfection after liver transplantation using entecavir monotherapy after short-term HBIg administration: A pilot study

Summary

EudraCT number	2008-005976-28
Trial protocol	DE
Global end of trial date	17 November 2015

Results information

Result version number	v1 (current)
This version publication date	12 January 2024
First version publication date	12 January 2024

Trial information

Trial identification

Sponsor protocol code	ETV-after-HBV-related-LTx

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01046799
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hannover Medical School
Sponsor organisation address	Carl-Neuberg-Str. 1, Hannover, Germany, 30625
Public contact	Zentrum für Klinische Studien, Hannover Medical School, EudraCT@mh-hannover.de
Scientific contact	Zentrum für Klinische Studien, Hannover Medical School, EudraCT@mh-hannover.de

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	23 December 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 November 2015
Global end of trial reached?	Yes
Global end of trial date	17 November 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this trial is to demonstrate that entecavir monotherapy in patients w/o lamivudine resistance or entecavir + tenofovir in patients with preexisting lamivudine resistance is able to prevent HBV reinfection defined by reappearance of HBsAg after liver transplantation only after short-term HBIG administration.

Protection of trial subjects:

The clinical trial was conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and with the standards of International Conference on Harmonisation (ICH) Good Clinical Practice (GCP). A continuous risk assessment was performed during the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 February 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Eligibility will be determined based upon the inclusion and exclusion criteria.

Period 1

Period 1 title	subjects at week 48 (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	subjects at week 48
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Entecavir
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Antiviral prophylaxis for hepatitis B with entecavir is given until the end of the study period of 96 weeks. Up until screening (planned for up to 84 days after liver transplantation) human hepatitis B immunoglobuline is administered ac-cording to standard protocol at the respective transplant centre (usually to keep anti-HBs>100). Tenofovir was added as a second nucleotide analogue in case of lamivudine resistance or pretreatment with tenofovir or according to the physicians discretion.

Number of subjects in period 1[1]	subjects at week 48
Started	16
Completed	16

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 20 subjects were enrolles but only 16 attended the visit at week 48, the endpoint and the baseline characteristics are only reported for those 16 subjects

Baseline characteristics

Reporting groups	
Reporting group title	subjects at week 48

Reporting group description: -

Reporting group values	subjects at week 48	Total	
Number of subjects	16	16	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	49		
standard deviation	± 7.7	-	
Gender categorical Units: Subjects			
Female	6	6	
Male	10	10	

End points

End points reporting groups

Reporting group title	subjects at week 48

Reporting group description: -

Primary: HBsAg negativity at 48w after LTx

End point title	HBsAg negativity at 48w after LTx[1]

End point description:

The primary objective of this pilot study is to demonstrate that entecavir monotherapy in patients without lamivudine resistance or entecavir + tenofo-vir in patients with preexisting lamivudine resistance is able to prevent HBV reinfection defined by reappearance of HBsAg after liver transplantation only after short-term HBIG administration. HBsAg negativity that is maintained for one year is a good surrogate parameter for prolonged HBsAg negativity with effective prophylaxis since HBV reinfection often occurs during the first 12 months of HBIG withdrawal.

End point type	Primary

End point timeframe:

48 weeks after liver transplantation

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: there were no further statistcal analyses done for this endpoint. Only total number of patients with HBsAG negativity at 48 weeks after LTx was measured. No p value etc is given

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs are reported for folllow up until week 120

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	all patients

Reporting group description: -

Serious adverse events	all patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 20 (75.00%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
Investigations			
ALT increased			
subjects affected / exposed	9 / 20 (45.00%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
Blood bilirubin increased			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
lung and liver metastasis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Injury, poisoning and procedural complications			
Fracture			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
postoperative hemorrhage			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
ERCP			
subjects affected / exposed	15 / 20 (75.00%)		
occurrences causally related to treatment / all	0 / 27		
deaths causally related to treatment / all	0 / 0		
liver biopsy			
subjects affected / exposed	9 / 20 (45.00%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		
coiling			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
prostate resection			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
cognitive disturbance			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Extrapyramidal disorder			

subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Fever			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pain			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	5 / 20 (25.00%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Portal vein thrombosis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
other	Additional description: infection under the liver capsule		
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Pruritus			

subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Purpura			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
naevus cell naevus			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Urinary tract obstruction			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
bronchial infection			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
CMV infection			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Biliary tract infection			
subjects affected / exposed	9 / 20 (45.00%)		
occurrences causally related to treatment / all	0 / 9		
deaths causally related to treatment / all	0 / 0		

Pancreas infection			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Sinusitis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
unspecific			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	all patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 20 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
lung and liver metastasis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Prostate cancer			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
hot flash			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Hypertension			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		

Hypotension			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Aneurysm			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Surgical and medical procedures			
ERCP			
subjects affected / exposed	20 / 20 (100.00%)		
occurrences (all)	27		
liver biopsy			
subjects affected / exposed	16 / 20 (80.00%)		
occurrences (all)	16		
coiling			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
prostate resection			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
edema limbs			
subjects affected / exposed	6 / 20 (30.00%)		
occurrences (all)	6		
Fatigue			
subjects affected / exposed	8 / 20 (40.00%)		
occurrences (all)	8		
fever			
subjects affected / exposed	7 / 20 (35.00%)		
occurrences (all)	7		
Malaise			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Pain			

subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Erectile dysfunction			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
irregular menstruation			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Prostatic obstruction			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 20 (25.00%)		
occurrences (all)	5		
dyspnea			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Hypoxia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Pleural effusion			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
postnasal drip			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
immobile diaphragm			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Psychiatric disorders			

Agitation subjects affected / exposed occurrences (all) Depression subjects affected / exposed occurrences (all) Insomnia subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3 4 / 20 (20.00%) 4 4 / 20 (20.00%) 4		
Investigations ALT increased subjects affected / exposed occurrences (all) Blood bilirubin increased subjects affected / exposed occurrences (all) weight gain subjects affected / exposed occurrences (all) weight loss subjects affected / exposed occurrences (all)	9 / 20 (45.00%) 9 4 / 20 (20.00%) 4 2 / 20 (10.00%) 2 4 / 20 (20.00%) 4		
Injury, poisoning and procedural complications Fall subjects affected / exposed occurrences (all) Fracture subjects affected / exposed occurrences (all) Hip fracture subjects affected / exposed occurrences (all) postoperative hemorrhage subjects affected / exposed occurrences (all) Wound complication	1 / 20 (5.00%) 1 1 / 20 (5.00%) 1 1 / 20 (5.00%) 1 1 / 20 (5.00%) 1		

subjects affected / exposed	7 / 20 (35.00%)		
occurrences (all)	7		
Cardiac disorders			
Palpitations			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Sinus bradycardia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Supraventricular tachycardia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Ventricular arrhythmia			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Nervous system disorders			
Amnesia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Ataxia			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
cognitive disturbance			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
concentration impairment			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Extrapyramidal disorder			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Headache			

subjects affected / exposed occurrences (all)	13 / 20 (65.00%) 13		
paresthesia subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
Tremor subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2		
vasovagal reaction subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Blood and lymphatic system disorders anemia subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3		
abnormal laboratory results subjects affected / exposed occurrences (all)	20 / 20 (100.00%) 20		
low platelets subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Ear and labyrinth disorders hearing impaired subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Tinnitus subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Eye disorders blurred vision subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1		
Gastrointestinal disorders			

Abdominal distension				
subjects affected / exposed	6 / 20 (30.00%)			
occurrences (all)	6			
Abdominal pain				
subjects affected / exposed	20 / 20 (100.00%)			
occurrences (all)	21			
Ascites				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences (all)	1			
bloating				
subjects affected / exposed	4 / 20 (20.00%)			
occurrences (all)	4			
Constipation				
subjects affected / exposed	3 / 20 (15.00%)			
occurrences (all)	3			
Diarrhoea				
subjects affected / exposed	4 / 20 (20.00%)			
occurrences (all)	4			
Dry mouth				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences (all)	1			
Enterocolitis				
subjects affected / exposed	3 / 20 (15.00%)			
occurrences (all)	3			
Oesophagitis				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences (all)	1			
Haemorrhoids				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences (all)	1			
mucositis oral				
subjects affected / exposed	1 / 20 (5.00%)			
occurrences (all)	1			
Nausea				
subjects affected / exposed	4 / 20 (20.00%)			
occurrences (all)	4			

Pancreatitis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Periodontal disease			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Proctitis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Hepatobiliary disorders			
Bile duct stenosis			
subjects affected / exposed	7 / 20 (35.00%)		
occurrences (all)	7		
Portal vein thrombosis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
infection under the liver capsule			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Skin and subcutaneous tissue disorders			
bullous dermatitis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Dry skin			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Hyperhidrosis			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
nail discoloration			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Pruritus			

subjects affected / exposed	12 / 20 (60.00%)		
occurrences (all)	12		
Purpura			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
naevus cell naevus			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 20 (20.00%)		
occurrences (all)	4		
Urinary tract pain			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Urinary tract obstruction			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Endocrine disorders			
struma uninodosa			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Hyperthyroidism			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Back pain			
subjects affected / exposed	8 / 20 (40.00%)		
occurrences (all)	8		
Bone pain			

subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
chest wall pain			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Flank pain			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
generalised muscle weakness			
subjects affected / exposed	5 / 20 (25.00%)		
occurrences (all)	5		
muscle weakness upper limb			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Myalgia			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Neck pain			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Osteoporosis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Infections and infestations			
bronchial infection			
subjects affected / exposed	6 / 20 (30.00%)		
occurrences (all)	6		
CMV infection			
subjects affected / exposed	4 / 20 (20.00%)		
occurrences (all)	4		
Biliary tract infection			
subjects affected / exposed	9 / 20 (45.00%)		
occurrences (all)	9		

Kidney infection subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1			
Laryngitis subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1			
mucosal infections subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2			
Pancreas infection subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2			
Pharyngitis subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1			
Sepsis subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1			
Sinusitis subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1			
Skin infection subjects affected / exposed occurrences (all)	2 / 20 (10.00%) 2			
unspecific subjects affected / exposed occurrences (all)	4 / 20 (20.00%) 4			
Metabolism and nutrition disorders Acidosis subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1			
anorexia subjects affected / exposed occurrences (all)	3 / 20 (15.00%) 3			
Hyperglycaemia				

subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Obesity			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Iron deficiency			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 December 2011	Amendment 04 : prolongation of recruitment period until 30.6.2013

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported