Clinical trial results:
Impact de la TEP dans la stratégie diagnostique des fièvres d'origine indéterminée ou des syndromes inflammatoires nus chez l'adulte immunocompétent.

Summary

EudraCT number	2007-005823-14
Trial protocol	FR
Global end of trial date	01 May 2013

Results information

Result version number	v1 (current)
This version publication date	04 June 2021
First version publication date	04 June 2021
Summary attachment (see zip file)	statistical report (FUO-TEP Rapport Statistique SD 20190730.pdf)

Trial information

Trial identification

Sponsor protocol code	I07005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01200771
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Limoges University Hospital
Sponsor organisation address	2 avenue Martin Luther King, LIMOGES, France, 87042
Public contact	Pr Kim LY, Limoges University Hospital, +33 555058076, kim.ly@chu-limoges.fr
Scientific contact	Pr Kim LY, Limoges University Hospital, +33 555058076, kim.ly@chu-limoges.fr

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	Interim
Date of interim/final analysis	21 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 May 2013
Global end of trial reached?	Yes
Global end of trial date	01 May 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluer la rentabilité diagnostique de la TEP (proportion de patients chez qui le diagnostic étiologique est réalisé grâce à la TEP), réalisé précocement, chez un groupe de patients présentant une fièvre prolongée d'origine indéterminée (FUO) ou un syndrome inflammatoire nu.

Protection of trial subjects:

Non protection specific

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 May 2008
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	France: 111
Worldwide total number of subjects	111
EEA total number of subjects	111

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)	65
From 65 to 84 years	44
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

no pre-assignment period

Period 1

Period 1 title	overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	all patients

Arm description: -

Arm type	Experimental
Investigational medicinal product name	18FDG
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Dosage and administration folowed the SPCs

Number of subjects in period 1	all patients
Started	111
Completed	103
Not completed	8
secondary exclusion	8

Baseline characteristics

Reporting groups	
Reporting group title	overall study

Reporting group description: -

Reporting group values	overall study	Total	
Number of subjects	111	111	
Age categorical Units: Subjects			
Adults (18-64 years)	65	65	
From 65-84 years	44	44	
85 years and over	2	2	
Age continuous Units: years			
median	58.2		
standard deviation	± 16.7	-	
Gender categorical Units: Subjects			
Female	52	52	
Male	59	59	

Subject analysis sets	
Subject analysis set title	all patients
Subject analysis set type	Intention-to-treat

Subject analysis set description:
patients with TEP and scanner

Reporting group values	all patients		
Number of subjects	103		
Age categorical Units: Subjects			
Adults (18-64 years)	61		
From 65-84 years	41		
85 years and over	1		
Age continuous Units: years			
median	58.2		
standard deviation	± 16.7		
Gender categorical Units: Subjects			
Female	50		
Male	53		

End points

End points reporting groups

Reporting group title	all patients
Reporting group description: -	
Subject analysis set title	all patients
Subject analysis set type	Intention-to-treat
Subject analysis set description: patients with TEP and scanner	

Primary: Assess the contribution of FDG-PET/CT in the early diagnostic work-up of patients with FUO or chronic inflammatory syndrome

End point title	Assess the contribution of FDG-PET/CT in the early diagnostic work-up of patients with FUO or chronic inflammatory syndrome[1]
End point description:	
End point type	Primary
End point timeframe: 3 month	

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: see statistical report joined

End point values	all patients			
Subject group type	Reporting group			
Number of subjects analysed	103			
Units: number	20			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

overall study

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	all patients

Reporting group description: -

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: no EA recolted for this study, only SAE

Serious adverse events	all patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 103 (6.80%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	2		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Injury, poisoning and procedural complications			
Wrist fracture			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Headache coma hemiplegia			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
headache vomiting			

subjects affected / exposed	1 / 103 (0.97%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory, thoracic and mediastinal disorders			
Respiratory distress			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Septic shock			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	all patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 103 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 August 2010	prolongation of inclusion period
20 June 2011	prolongation of inclusion period increasing of inclusion number update of patient following

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported