Clinical trial results:
The effects of PXR activation on hepatic fat content

Summary

EudraCT number	2014-003422-41
Trial protocol	FI
Global end of trial date	01 February 2018

Results information

Result version number	v1 (current)
This version publication date	08 March 2022
First version publication date	08 March 2022

Trial information

Trial identification

Sponsor protocol code	Rifa-Stea

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02329405
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Oulu University Hospital
Sponsor organisation address	Kajaanintie 50, Oulu, Finland,
Public contact	janne.hukkanen@oulu.fi, Oulu University Hospital, Department of Internal Medicine, 358 83156212, janne.hukkanen@oulu.fi
Scientific contact	janne.hukkanen@oulu.fi, Oulu University Hospital, Department of Internal Medicine, 358 83156212, janne.hukkanen@oulu.fi

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	15 February 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 February 2018
Global end of trial reached?	Yes
Global end of trial date	01 February 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study how PXR activation by rifampicin affects hepatic fat content

Protection of trial subjects:

Basic laboratory measures controlled to ensure safety of using rifampicin.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 November 2014
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	Finland: 17
Worldwide total number of subjects	17
EEA total number of subjects	17

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)	17
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Healthy volunteers responding to recruitment add in email list.

Pre-assignment

Screening details:

Healthy volunteers responding to recruitment add in email list. Screened and randomized to two-arm crossover study.

Period 1

Period 1 title	Screening and randomization (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Rifampicin arm

Arm description:

Rifampicin 600 mg daily for one week

Arm type	Experimental
Investigational medicinal product name	Rifampicin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

600 mg daily for a week

Arm title	Placebo arm

Arm description:

Placebo daily for a week.

Arm type	Placebo
Investigational medicinal product name	Placebo (contains magnesium stearate, microcrystalline cellulose)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet once daily for a week.

Number of subjects in period 1	Rifampicin arm	Placebo arm
Started	16	17
Completed	16	16
Not completed	0	1
Adverse event, non-fatal	-	1

Baseline characteristics

Reporting groups

Reporting group title	Screening and randomization

Reporting group description: -

Reporting group values	Screening and randomization	Total	
Number of subjects	17	17	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	17	17	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	23		
standard deviation	± 3	-	
Gender categorical Units: Subjects			
Female	6	6	
Male	11	11	

End points

End points reporting groups

Reporting group title	Rifampicin arm
Reporting group description: Rifampicin 600 mg daily for one week	
Reporting group title	Placebo arm
Reporting group description: Placebo daily for a week.	

Primary: Hepatic fat

End point title	Hepatic fat
End point description:	
End point type	Primary
End point timeframe: After one-week of rifampicin/placebo	

End point values	Rifampicin arm	Placebo arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: Arbitary unit				
arithmetic mean (standard deviation)	2.45 (± 1.7)	2.53 (± 2.4)		

Statistical analyses

Statistical analysis title	Student t-test
Comparison groups	Placebo arm v Rifampicin arm
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	> 0.05
Method	t-test, 2-sided

Notes:

[1] - EudraCT system does not understand crossover analysis, thus, there is only 16 subjects.

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
One-week study arms	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups	
Reporting group title	Rifampicin arm
Reporting group description: -	
Reporting group title	Placebo arm
Reporting group description: -	

Serious adverse events	Rifampicin arm	Placebo arm	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Rifampicin arm	Placebo arm	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 16 (43.75%)	3 / 17 (17.65%)	
General disorders and administration site conditions			
Bad taste in mount			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	2 / 16 (12.50%)	1 / 17 (5.88%)	
occurrences (all)	2	1	
Appetite disorder	Additional description: Lack of appetite		
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Constipation			
subjects affected / exposed	1 / 16 (6.25%)	0 / 17 (0.00%)	
occurrences (all)	1	0	
Liver function test increased			
subjects affected / exposed	0 / 16 (0.00%)	1 / 17 (5.88%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Upper respiratory tract infection			
subjects affected / exposed	2 / 16 (12.50%)	1 / 17 (5.88%)	
occurrences (all)	2	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported