Clinical trial results:
Accelerated wound healing in diabetic ulcers by Sitagliptin

Summary

EudraCT number	2015-005226-19
Trial protocol	AT
Global end of trial date	19 September 2016

Results information

Result version number	v1 (current)
This version publication date	13 November 2020
First version publication date	13 November 2020

Trial information

Trial identification

Sponsor protocol code	SitaDFU_v1.0

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02675335
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52 A, Innsbruck, Austria, 6020
Public contact	Clinical Trials Center - Cardiology, Medical University of Innsbruck Dept. for Internal Medicine III Anichstrasse 35 6020 innsbruck, 43 51250425636, lki.me.studien-cardio@tirol-kliniken.at
Scientific contact	Clinical Trials Center - Cardiology, Medical University of Innsbruck Dept. for Internal Medicine III Anichstrasse 35 6020 innsbruck, 43 51250425636, lki.me.studien-cardio@tirol-kliniken.at

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	19 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 September 2016
Global end of trial reached?	Yes
Global end of trial date	19 September 2016
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the effect of Sitagliptin on healing of stable, non-healing diabetic foot ulcers. Quantification of ulcer size will be measured from baseline to 3 months follow-up using planimetry of the wound to compare the difference in mean ulcer size between treatment groups.

Protection of trial subjects:

N/A

Background therapy:

N/A

Evidence for comparator:

N/A

Actual start date of recruitment	09 August 2016
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	Austria: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No subjects were recruited for this trial. "99999" is a value for 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Arm title	Sitagliptin/ Placebo group

Arm description:

No patients were enrolled in this trial. "99999" is a value for 0 participants.

Arm type	Experimental
Investigational medicinal product name	Sitagliptin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Sitagliptin would have been administered orally as tablets of 100mg once daily for a period of 12 weeks.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo would have been administered orally as tablets of 100mg once daily for a period of 12 weeks.

Number of subjects in period 1	Sitagliptin/ Placebo group
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Treatment period
Reporting group description:	
No patients were enrolled in this trial. "99999" is a value for 0 participants.	

Reporting group values	Treatment period	Total	
Number of subjects	99999	99999	
Age categorical			
No patients were enrolled in this trial. "99999" is a value for 0 participants.			
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)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
No patients were renrolled in this trial. "99999" is a value for 0 participants.			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical			
No patients were enrolled in this trial. "99999" is a value for 0 participants.			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Sitagliptin/ Placebo group

Reporting group description:

No patients were enrolled in this trial. "99999" is a value for 0 participants.

Primary: Ulcer size

End point title	Ulcer size[1]

End point description:

End point type	Primary

End point timeframe:

N/A

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: No subjects were enrolled in this trial, therefore no statistical analysis was done.

End point values	Sitagliptin/ Placebo group			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: N/A				
number (not applicable)	99999			

Notes:

[2] - "99999" is a value for 0 participants

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 09.08..2016-19.09.2016	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	4.03

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

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 subjects were enrolled in this trial, therefore no AEs or SAEs were observed.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in this trial. "99999" is a value for 0 participants, as it was not possible to fill in "0" for the number of included patients.

Notes: