Clinical trial results:
Pilot study to evaluate glycemic control with GlucoTab using an ultra-long acting insulin analogue in non-critically ill patients with type 2 diabetes at the genaral ward

Summary

EudraCT number	2018-002646-36
Trial protocol	AT
Global end of trial date	24 March 2020

Results information

Result version number	v1 (current)
This version publication date	18 June 2022
First version publication date	18 June 2022

Trial information

Trial identification

Sponsor protocol code	GlucoTab_Degludec

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical Univerity of Graz, Department of Internal Medicine, Division for Endocrinology & Diabetology
Sponsor organisation address	Auenbruggerplatz 215, Graz, Austria, 8036
Public contact	Assoc. Prof. PD Dr. Julia Mader, Medical University of Graz Department of Internal Medicine, Division for Endocrinology & Diabetolog, 0043 316385 80254, julia.mader@medunigraz.at
Scientific contact	Assoc. Prof. PD Dr. Julia Mader, Medical University of Graz Department of Internal Medicine, Division for Endocrinology & Diabetolog, 0043 316385 80254, julia.mader@medunigraz.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	29 November 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 March 2020
Global end of trial reached?	Yes
Global end of trial date	24 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the efficacy of the GlucoTab system for glycemic management using insulin degludec in non-critically ill patients with type 2 diabetes at the general ward

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki and ICH Good Clinical Practice. All study participants were required to read and sign an Informed Consent Form.

Background therapy:

variable

Evidence for comparator:

na

Actual start date of recruitment	16 January 2020
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: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	7
From 65 to 84 years	17
85 years and over	6

Subject disposition

Recruitment

Recruitment details:

Hospitalized patients with Type 2 Diabetes at the Endocrinological ward of the Medical University of Graz were identified by the investigators for participation in this study.

Pre-assignment

Screening details:

30 subjects signed the Informed Consent and could be included in the study.

Period 1

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

Arms

Arm title	single arm

Arm description:

The investigational treatment is insulin therapy using the GlucoTab system with insulin degludec as the long-acting basal insulin and insulin aspart as bolus insulin to cover meals and correct elevated blood glucose levels.

Arm type	Experimental
Investigational medicinal product name	Insulin degludec
Investigational medicinal product code	
Other name	Insulin degludec
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

variable

Number of subjects in period 1	single arm
Started	30
Completed	30

Baseline characteristics

Reporting groups

Reporting group title	overall trial

Reporting group description:

Insulin therapy will be adjusted according to the GlucoTab system with incorporated software algorithm. Participants will be treated with the GlucoTab and its integrated algorithm for basal bolus therapy using insulin degludec and insulin aspart. The goal of the GlucoTab system was to maintain fasting and
pre-meal glucose concentrations between 70-140mg/dl. The glucose measurements was be performed-prandially and at bedtime by nursing staff.

Reporting group values	overall trial	Total	
Number of subjects	30	30	
Age categorical			
Adults			
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	6	6	
85 years and over	7	7	
Gender categorical			
all gender			
Units: Subjects			
Female	18	18	
Male	12	12	
all ethnic groups Units: Subjects			
caucasian	30	30	

Subject analysis sets

Subject analysis set title	Total study
Subject analysis set type	Per protocol

Subject analysis set description:

Patients with type 2 diabetes or newly diagnosed hyperglycemia requiring subcutaneous insulin therapy.

Subject analysis set title	Workaround for t-test
Subject analysis set type	Per protocol

Subject analysis set description:

EudraCT & EU CTR Frequently asked questions (p.23):
In order to report a statistical analysis related to a specific endpoint it is required to define at least two comparison groups. In order to report a single arm trial, a workaround needs to be performed.

Reporting group values	Total study	Workaround for t-test	
Number of subjects	30	30	
Age categorical			
Adults			
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)	6		
From 65-84 years	17		
85 years and over	7		
Gender categorical			
all gender			
Units: Subjects			
Female	18		
Male	12		
all ethnic groups Units: Subjects			
caucasian	30		

End points

End points reporting groups

Reporting group title	single arm

Reporting group description:

The investigational treatment is insulin therapy using the GlucoTab system with insulin degludec as the long-acting basal insulin and insulin aspart as bolus insulin to cover meals and correct elevated blood glucose levels.

Subject analysis set title	Total study
Subject analysis set type	Per protocol

Subject analysis set description:

Patients with type 2 diabetes or newly diagnosed hyperglycemia requiring subcutaneous insulin therapy.

Subject analysis set title	Workaround for t-test
Subject analysis set type	Per protocol

Subject analysis set description:

EudraCT & EU CTR Frequently asked questions (p.23):
In order to report a statistical analysis related to a specific endpoint it is required to define at least two comparison groups. In order to report a single arm trial, a workaround needs to be performed.

Primary: Mean percentage of blood glucose measurements in the target range 70 to 140 mg/dl

End point title	Mean percentage of blood glucose measurements in the target range 70 to 140 mg/dl

End point description:

End point type	Primary

End point timeframe:

total study duration

End point values	Total study	Workaround for t-test		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	30	30		
Units: percentage				
number (not applicable)	52.2	42.0		

Statistical analyses

Statistical analysis title	Weighted one-sided, one-sample t-test
Comparison groups	Total study v Workaround for t-test

Number of subjects included in analysis	60
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0093
Method	t-test, 1-sided
Parameter estimate	Mean difference (final values)
Point estimate	10.2
Confidence interval	
level	95 %
sides	1-sided
lower limit	3.5
Variability estimate	Standard error of the mean
Dispersion value	4.1

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse events were assessed during the total study period	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23

Reporting groups	
Reporting group title	total study

Reporting group description: -

Serious adverse events	total study		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 30 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	total study		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 30 (43.33%)		
Vascular disorders			
Thrombosis	Additional description: superficial vein: V. saphena parva dext.		
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Eye disorders			

anisocoria dextra			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Gastrointestinal disorders			
Cholecystitis acute			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Pneumonia			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Thoracic pain			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
inguinal intertriginous dermatitis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Renal and urinary disorders			
Urinary tract infection			
subjects affected / exposed	2 / 30 (6.67%)		
occurrences (all)	2		
Musculoskeletal and connective tissue disorders			
Pain in extremity	Additional description: Pain in left arm - suspected psoriatic arthritis		
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Osteoporosis			
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Infections and infestations			
Infection of unknown origin	Additional description: elevated CRP		
subjects affected / exposed	1 / 30 (3.33%)		
occurrences (all)	1		
Metabolism and nutrition disorders			

Vitamin D deficiency subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 1		
Hyperlipidaemia subjects affected / exposed occurrences (all)	1 / 30 (3.33%) 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

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

na

Notes: