Clinical trial results:
A single-centre, open-label, non-controlled trial of acceptance, usability, safety and efficacy of a tablet based workflow and decision support system with incorporated basal-insulin algorithm for glycaemic management in patients with type 2 diabetes receiving domiciliary nursing care

Summary

EudraCT number	2018-000863-98
Trial protocol	AT
Global end of trial date	30 October 2018

Results information

Result version number	v1 (current)
This version publication date	27 October 2021
First version publication date	27 October 2021

Trial information

Trial identification

Sponsor protocol code	GlucoTab@MobileCare

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	German Clinical Trials Register : DRKS00015059

Notes:

Sponsors

Sponsor organisation name	Medical University of Graz, Univ. Prof. Dr. Thomas Pieber, Department of Internal Medicine, Division of Endocrinology and Diabetology
Sponsor organisation address	Auenbruggerplatz 15, Graz, Austria, 8036
Public contact	Sponsor contact, Medical University of Graz/Department of Internal Medicine/Division of Endocrinology and Diabetology, 0043 316385-72766, julia.kopanz@medunigraz.at
Scientific contact	Sponsor contact, Medical University of Graz/Department of Internal Medicine/Division of Endocrinology and Diabetology, 0043 316385-72766, julia.kopanz@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	23 May 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 October 2018
Global end of trial reached?	Yes
Global end of trial date	30 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the acceptance of the GlucoTab@MobileCare system for glycaemic management in patients with type 2 diabetes receiving domiciliary nursing care

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: -

Evidence for comparator: -

Actual start date of recruitment	10 July 2018
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: 9
Worldwide total number of subjects	9
EEA total number of subjects	9

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)	1

From 65 to 84 years	6
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Single-centre study - 1 site in Austria
Recruitment started on 10-Jul-2018. Potential study participants were identified by domiciliary nurses of participating centers. Patients interested in the study were subsequently visited by one of the investigators. Altogether, 10 type 2 diabetes patients were included.

Pre-assignment

Screening details:

From the 10 included patients, 8 completed the study according to study protocol, 1 was hospitalized (death) and 1 withdrew before any study related therapy had started. As the patient who got hospitalized had fulfilled the planned treatment duration, data was included for analyses. In total, data of 9 patients has been analyzed.

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	GlucoTab@MobileCare

Arm description:

Insulin therapy with basal-insulin (Toujeo® Solostar®) was initiated and adjusted according to GlucoTab@MobileCare with incorporated basal-insulin algorithm. The goal of the basal-insulin algorithm was to maintain FBG within the FBG target according to the predefined health status. After start, basal-insulin was administered once daily in the morning. BG corrections with short acting insulin for very high BG values were performed using insulin glulisine Apidra® Solostar®.
Capillary BG was measured by the nurses three times daily before meals at least for the first three days of the basal-insulin algorithm and only once in the morning when basal-insulin therapy had proven to be the suitable therapy regime (when BG values didn't rise by more than 150 mg/dL compared to the FBG). For the long-term treatment, GlucoTab@MobileCare recommended one day with three pre-meal BG measurements once a month.

Arm type	Experimental
Investigational medicinal product name	Toujeo 300 Einheiten/ml-Injektionslösung in einem Fertigpen
Investigational medicinal product code	ATC-Code: A10A E04
Other name	Toujeo®, Sanofi-Aventis (insulin glargine U300)
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Insulin dosage calculation was performed according to GlucoTab@MobileCare under supervision of the district nurses. If necessary, investigators could be contacted and reviewed the GlucoTab@MobileCare suggestion for correctness and plausibility. The insulin was administered sc via insulin pen by the nurses. Dosage was adjusted per individual patient requirements. Basal insulin was administered once daily.

Investigational medicinal product name	Apidra SoloStar 100 Einheiten/ml-Injektionslösung in einem Fertigpen
Investigational medicinal product code	ATC-Code: A10A B06
Other name	Apidra®, Sanofi-Aventis (insulin glulisine)
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

BG corrections with short acting insulin for very high BG values was performed according to GlucoTab@MobileCare suggestions. Correctional bolus insulin was administered at defined time-points according to BG targets in the predefined health status. The insulin was administered sc via insulin pen by the nurses. Dosage was adjusted per individual patient requirements.

Number of subjects in period 1	GlucoTab@MobileCare
Started	9
Completed	8
Not completed	1
Adverse event, serious fatal	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description:

Insulin therapy with basal-insulin (Toujeo® Solostar®) was initiated and adjusted according to GlucoTab@MobileCare with incorporated basal-insulin algorithm. The goal of the basal-insulin algorithm was to maintain FBG within the FBG target according to the predefined health status. After start, basal-insulin was administered once daily in the morning. BG corrections with short acting insulin for very high BG values were performed using insulin glulisine Apidra® Solostar®.
Capillary BG was measured by the nurses three times daily before meals at least for the first three days of the basal-insulin algorithm and only once in the morning when basal-insulin therapy had proven to be the suitable therapy regime (when BG values didn't rise by more than 150 mg/dL compared to the FBG). For the long-term treatment, GlucoTab@MobileCare recommended one day with three pre-meal BG measurements once a month.

Reporting group values	Overall trial	Total	
Number of subjects	9	9	
Age categorical Units: Subjects			
Adults (18-64 years)	1	1	
From 65-84 years	6	6	
85 years and over	2	2	
Age continuous Units: years			
arithmetic mean	77.1		
standard deviation	± 9.8	-	
Gender categorical Units: Subjects			
Female	5	5	
Male	4	4	
Individual health status Units: Subjects			
tight	1	1	
moderate	6	6	
loose	2	2	
HbA1c at screening Units: mmol/mol			
arithmetic mean	59.5		
standard deviation	± 12.8	-	
HbA1c at study end Units: mmol/mol			
arithmetic mean	56.5		
standard deviation	± 12.4	-	

End points

End points reporting groups

Reporting group title	GlucoTab@MobileCare

Reporting group description:

Insulin therapy with basal-insulin (Toujeo® Solostar®) was initiated and adjusted according to GlucoTab@MobileCare with incorporated basal-insulin algorithm. The goal of the basal-insulin algorithm was to maintain FBG within the FBG target according to the predefined health status. After start, basal-insulin was administered once daily in the morning. BG corrections with short acting insulin for very high BG values were performed using insulin glulisine Apidra® Solostar®.
Capillary BG was measured by the nurses three times daily before meals at least for the first three days of the basal-insulin algorithm and only once in the morning when basal-insulin therapy had proven to be the suitable therapy regime (when BG values didn't rise by more than 150 mg/dL compared to the FBG). For the long-term treatment, GlucoTab@MobileCare recommended one day with three pre-meal BG measurements once a month.

Primary: The percentage of tasks (BG measurements, insulin dose calculations, insulin injections) that were performed according to GlucoTab@MobileCare with respect to all suggested tasks.

End point title	The percentage of tasks (BG measurements, insulin dose calculations, insulin injections) that were performed according to GlucoTab@MobileCare with respect to all suggested tasks.[1]

End point description:

End point type	Primary

End point timeframe:

whole study duration

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: All parameters were analysed by descriptive and explorative statistical methods. No hypotheses were tested. The primary endpoint was: Percentage of tasks (BG measurements, insulin dose calculations, insulin injections) that were performed according to GlucoTab@MobileCare with respect to all suggested tasks.

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: percentage of tasks	95			

Statistical analyses

No statistical analyses for this end point

Secondary: Adherence to GlucoTab@MobileCare suggestions

End point title	Adherence to GlucoTab@MobileCare suggestions

End point description:

End point type	Secondary

End point timeframe:

whole study duration

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage				
number (not applicable)				
Adherence to suggested BG measuremnt frequency	94.9			
Adherence to suggested basal ins. titration dose	95.9			
Adherence to suggested basal ins. injection dose	99.7			
Adherence to suggested bolus ins. injection dose	97.9			
Adherence to suggested time point of titrations	100			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean adherence to suggested BG measurement frequency, basal and bolus insulin injection dose

End point title	Mean adherence to suggested BG measurement frequency, basal and bolus insulin injection dose

End point description:

End point type	Secondary

End point timeframe:

whole study duration, on weekdays only

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage				
arithmetic mean (standard deviation)				
Adherence to suggested BG measurement frequency	94.9 (± 3.6)			
Adherence to suggested basal ins. titration dose	95.9 (± 3.2)			
Adherence to suggested basal ins. injection dose	99.7 (± 0.5)			
Adherence to suggested bolus ins. injection dose	79.4 (± 44.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: BG values below individual target range

End point title	BG values below individual target range
End point description: altogether 25 BG values were below individual target	
End point type	Secondary
End point timeframe: whole study duration	

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage				
arithmetic mean (standard deviation)				
Fasting BG below individual target	2.1 (± 1.8)			
Morning BG below individual target	0 (± 0)			
Midday BG below individual target	0.3 (± 0.6)			
Evening BG below individual target	0 (± 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of suggested/missed/performed insulin injections

End point title	Number of suggested/missed/performed insulin injections
End point description: Almost all 918 insulin injections suggested (1.2 ± 0.4) by the GlucoTab@MobileCare system were performed (n=914) (1.2 ± 0.4) and only four were missed (0.01 ± 0.07).	
End point type	Secondary
End point timeframe: whole study duration	

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage				
arithmetic mean (standard deviation)				
Suggested insulin injections	1.2 (± 0.4)			
Missed insulin injections	0.01 (± 0.07)			
Performed insulin injections	1.2 (± 0.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean BG values in different day times

End point title	Mean BG values in different day times

End point description:

End point type	Secondary

End point timeframe:

whole study duration for "mean morning BG", first 3 treatment days only for the other endpoints

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: mg/dl				
arithmetic mean (standard deviation)				
Mean daily BG (first 3 treatment days only)	221.1 (± 80.4)			
Mean morning BG (all treatment days)	156 (± 33.3)			
Mean lunchtime BG (first 3 treatment days only)	223.9 (± 76.1)			
Mean dinnertime BG (first 3 treatment days only)	226 (± 82)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of FBG values below/within/above FBG target range health status TIGHT

End point title	Percentage of FBG values below/within/above FBG target range health status TIGHT

End point description:

85 FBG measurements were taken in this group

End point type	Secondary

End point timeframe:

whole study duration

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage				
number (not applicable)				
BG below FBG range	4.7			
BG within FBG range	29.4			
BG above FBG range	65.9			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of FBG values below/within/above FBG target range health status MODERATE

End point title	Percentage of FBG values below/within/above FBG target range health status MODERATE

End point description:

491 FBG measurements were taken in this group

End point type	Secondary

End point timeframe:

whole study duration

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Percentage				
number (not applicable)				
BG below FBG range	2			
BG within FBG range	66.8			
BG above FBG range	31.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of FBG values below/within/above FBG target range health status LOOSE

End point title	Percentage of FBG values below/within/above FBG target range health status LOOSE
End point description: 144 FBG measurements were taken in this group	
End point type	Secondary
End point timeframe: whole study duration	

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Percentage				
number (not applicable)				
BG below FBG range	5.6			
BG within FBG range	52.8			
BG above FBG range	41.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of morning (post-prandial) BG values below/within/above FBG target range health status TIGHT

End point title	Percentage of morning (post-prandial) BG values below/within/above FBG target range health status TIGHT
End point description: no morning (post-prandial) BGs were taken in this group	
End point type	Secondary
End point timeframe: whole study duration	

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage				
number (not applicable)				
Morning BG below FBG range	0			
Morning BG within FBG range	0			
Morning BG above FBG range	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of morning (post-prandial) BG values below/within/above FBG target range health status MODERATE

End point title	Percentage of morning (post-prandial) BG values below/within/above FBG target range health status MODERATE
End point description:	
14 morning (post-prandial) BGs were taken in this group	
End point type	Secondary
End point timeframe:	
whole study duration	

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Percentage				
number (not applicable)				
Morning BG below FBG range	0			
Morning BG within FBG range	7.1			
Morning BG above FBG range	92.9			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of morning (post-prandial) BG values below/within/above FBG target range health status LOOSE

End point title	Percentage of morning (post-prandial) BG values below/within/above FBG target range health status LOOSE
End point description:	
20 morning (post-prandial) BG measurements were taken in the group with health status loose	
End point type	Secondary
End point timeframe:	
whole study duration	

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Percentage				
number (not applicable)				
Morning BG below FBG range	0			
Morning BG within FBG range	10			
Morning BG above FBG range	90			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of treatment days with morning BG or FBG values within FBG target range for health status TIGHT

End point title	Percentage of treatment days with morning BG or FBG values within FBG target range for health status TIGHT
End point description:	
86 treatment days with FBG or morning BG measurements in this group	
End point type	Secondary
End point timeframe:	
whole study duration	

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: Percentage				
number (not applicable)	29.1			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of treatment days with morning BG or FBG values within FBG target range for health status MODERATE

End point title	Percentage of treatment days with morning BG or FBG values within FBG target range for health status MODERATE
End point description:	
511 treatment days with FBG or morning BG measurements	
End point type	Secondary
End point timeframe:	
whole study duration	

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Percentage				
number (not applicable)	64.8			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of treatment days with morning BG or FBG values within FBG target range for health status LOOSE

End point title	Percentage of treatment days with morning BG or FBG values within FBG target range for health status LOOSE

End point description:

166 treatment days with FBG or morning BG measurements in this group

End point type	Secondary

End point timeframe:

whole study duration

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: Percentage				
number (not applicable)	47			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of treament days with BG values within the respective health-dependent target range

End point title	Percentage of treament days with BG values within the respective health-dependent target range

End point description:

Altogether 725 treatment days with FBG values, 38 treatment days with morning BG values (post-prandial), 123 treatment days with lunchtime BG values and 106 treatment days with dinnertime BG values.

End point type	Secondary

End point timeframe:
whole study duration

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage				
number (not applicable)				
treatment days with FBGs within target	59.5			
treatment days with morning BGs within target	7.9			
treatment days with lunchtime BGs within target	86.2			
treatment days with dinnertime BGs within target	90.6			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of treament days with BG values below the respective health-dependent target range

End point title	Percentage of treament days with BG values below the respective health-dependent target range

End point description:

Altogether 725 treatment days with FBG values, 38 treatment days with morning BG values (post-prandial), 123 treatment days with lunchtime BG values and 106 treatment days with dinnertime BG values.

End point type	Secondary

End point timeframe:
whole study duration

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage				
number (not applicable)				
treatment days with FBGs below target	3			
treatment days with morning BGs below target	0			
treatment days with lunchtime BGs below target	2.4			
treatment days with dinnertime BGs below target	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean insulin starting dose and mean insulin dose at last treament day

End point title	Mean insulin starting dose and mean insulin dose at last treament day

End point description:

End point type	Secondary

End point timeframe:

beginning and end of the treatment

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: IU				
arithmetic mean (standard deviation)				
insulin starting dose at first treatment day	24.2 (± 13.1)			
insulin starting dose of first 3 treatment days	25.6 (± 16)			
insulin dose at last treatment day	38.2 (± 30.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall percentage of BG values in pre-defined BG ranges

End point title	Overall percentage of BG values in pre-defined BG ranges

End point description:

End point type	Secondary

End point timeframe:

whole study duration

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage				
number (not applicable)				
0-69 mg/dl	0.3			
70-180 mg/dl	69			
> 180 mg/dl	30.8			
0-40 mg/dl	0			
0-53 mg/dl	0			
0-89 mg/dl	2.3			
70-130 mg/dl	31.1			
70-150 mg/dl	48.2			
100-180 mg/dl	63.5			
181-260 mg/dl	22.1			
261-349 mg/dl	7.4			
>= 350 mg/dl	1.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Morning BG values grouped by study month

End point title	Morning BG values grouped by study month

End point description:

Aggregation was performed over all BG values of all patients in a certain period of time. 761 BGs that were taken in the morning were analyzed.

End point type	Secondary

End point timeframe:

whole study duration

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: mg/dl				
arithmetic mean (standard deviation)				
Month 1	171 (± 68)			
Month 2	150 (± 46)			
Month 3	145 (± 35)			

Statistical analyses

No statistical analyses for this end point

Secondary: Morning BG in different ranges

End point title	Morning BG in different ranges

End point description:

Aggregation was performed over all BG values of all patients in a certain period of time. 761 BGs that were taken in the morning were analyzed.

End point type	Secondary

End point timeframe:

whole study duration

End point values	GlucoTab@MobileCare			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage				
number (not applicable)				
<54 mg/dl	0			
<70 mg/dl	0.3			
70-180 mg/dl	77			
>180 mg/dl	22.7			
>300 mg/dl	2.6			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse Events were assessed during whole study duration: Time range: 10.07.2018 (FPFV) – 30.10.2018 (LPLV)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23

Reporting groups

Reporting group title	GlucoTab@MobileCare

Reporting group description: -

Serious adverse events	GlucoTab@MobileCare		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 9 (11.11%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea, Cough, pressure on the chest	Additional description: The patient was referred to the emergency room due to dyspnea, cough, and pressure on the chest with suspicion of pneumonia and pleural effusion respectively.		
subjects affected / exposed	1 / 9 (11.11%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

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

Non-serious adverse events	GlucoTab@MobileCare		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 9 (44.44%)		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea	Additional description: Dyspnoea, cough		
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			

Erysipelas	Additional description: Erysipelas of lower right extremity		
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Renal and urinary disorders			
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Fall			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Contusion	Additional description: contusion dig III-IV ped sin		
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	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.

short duration of study; no control-group; Insulin as pre-therapy

Notes: