Clinical trial results:
A single-centre, open-label, randomized controlled trial of efficacy, safety and usability of a basal insulin algorithm incorporated in the GlucoTab system compared to standard care for glycaemic management in geriatric patients with type 2 diabetes at acute geriatric care wards

Summary

EudraCT number	2017-000955-25
Trial protocol	AT
Global end of trial date	05 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	ClinDiab-08

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	German Clinical Trials Register: DRKS00012553

Notes:

Sponsors

Sponsor organisation name	Geriatric Health Centres of the City of Graz, Austria
Sponsor organisation address	Albert Schweitzer Gasse 36, Graz, Austria, 8010
Public contact	Walter Schippinger, Geriatric Health Centres of the City of Graz, Austria, +43 31670601302, walter.schippinger@stadt.graz.at
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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	05 February 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	05 October 2018
Global end of trial reached?	Yes
Global end of trial date	05 October 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare efficacy of the basal-insulin algorithm (decision support) with computerized documentation (without decision support) incorporated in the GlucoTab system for glycaemic management in patients with type 2 diabetes at acute geriatric care wards

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	06 June 2017
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: 58
Worldwide total number of subjects	58
EEA total number of subjects	58

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)	0
From 65 to 84 years	49

85 years and over	9

Subject disposition

Recruitment

Recruitment details:

single-centre study - 1 site in Austria

Pre-assignment

Screening details:

60 patients signed the informed consent (IC). 31 patients were allocated to the intervention group (IG) and 29 patients to the control group (CG). All 31 patients in the IG received the allocated intervention. In the CG 27 patients received the allocated intervention (1 was erroneously screened, 1 withdrew the IC immedeately after randomization).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Decision support with GlucoTab - Intervention Group

Arm description:

Insulin therapy with basal insulin (insulin glargine U300) was started and adjusted according to GlucoTab with incorporated new basal-insulin software algorithm. The goal of the basal-insulin algorithm was to maintain fasting blood glucose within the FBG target according to the predefined health level. After start, basal insulin was administered once daily before breakfast. Insulin dosage prescription was performed according to GlucoTab under supervision of the treating physician. The total daily dose was reduced by 2 units if any BG value was below target and by 4 units if any BG value was ≥ 20 mg/dL below target. The total daily dose was raised according to a titration table. Capillary glucose was measured three times daily before meals at least for the first 3 days of algorithm-based treatment and only once in the morning when therapy was verified to be stable. Correctional bolus insulin was administered according to BG targets in the predefined health status.

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 prescription was performed according to GlucoTab under supervision of the treating physician. The total daily dose was reduced by 2 units if any BG value was below target and by 4 units if any BG value was ≥ 20 mg/dL below target. The total daily dose was raised according to a titration table. Several ways of therapy adjustment were supported by the system. The most important aspect was the basal insulin dose titration. In addition, blood glucose values over the day were analysed and physicians were informed if the increase over the day was higher than 150 mg/dL with the suggestion to a) adjust concomitant medication (oral antidiabetic or incretin agents – "basal insulin supported oral therapy / incretin therapy") b) add a short acting insulin once daily ("Basal plus therapy") or c) to use a therapy other than basal insulin if a) and b) were not successful or the total daily insulin dose was above a defined threshold.

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 were performed according to GlucoTab

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.

Arm title	Documentation only in GlucoTab - Control Group
Arm description:	
Study participants in the control group received standard insulin therapy as judged by the treating physician. This therapy was documented by the health professionals using the GlucoTab system with the feature "custom therapy" without decision support. BG measurements were performed according to the treating physician. To guarantee comparability between treatment and control group at least 3 BG measurements a day for the first three days and later at least FBG values had to be measured.	
Arm type	as judged by the treating physician
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group
Started	31	27
Completed	28	27
Not completed	3	0
Physician decision	1	-
Patient decision	1	-
Protocol deviation	1	-

Baseline characteristics

Reporting groups

Reporting group title	Decision support with GlucoTab - Intervention Group

Reporting group description:

Insulin therapy with basal insulin (insulin glargine U300) was started and adjusted according to GlucoTab with incorporated new basal-insulin software algorithm. The goal of the basal-insulin algorithm was to maintain fasting blood glucose within the FBG target according to the predefined health level. After start, basal insulin was administered once daily before breakfast. Insulin dosage prescription was performed according to GlucoTab under supervision of the treating physician. The total daily dose was reduced by 2 units if any BG value was below target and by 4 units if any BG value was ≥ 20 mg/dL below target. The total daily dose was raised according to a titration table. Capillary glucose was measured three times daily before meals at least for the first 3 days of algorithm-based treatment and only once in the morning when therapy was verified to be stable. Correctional bolus insulin was administered according to BG targets in the predefined health status.

Reporting group title	Documentation only in GlucoTab - Control Group

Reporting group description:

Study participants in the control group received standard insulin therapy as judged by the treating physician. This therapy was documented by the health professionals using the GlucoTab system with the feature "custom therapy" without decision support. BG measurements were performed according to the treating physician. To guarantee comparability between treatment and control group at least 3 BG measurements a day for the first three days and later at least FBG values had to be measured.

Reporting group values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group	Total
Number of subjects	31	27	58
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	25	24	49
85 years and over	6	3	9
Age continuous Units: years			
arithmetic mean	78	76	
standard deviation	± 6	± 6	-
Gender categorical Units: Subjects			
Female	20	17	37
Male	11	10	21
Individual health status Units: Subjects			
tight	8	7	15
moderate	23	20	43
loose	0	0	0

HbA1c at study start Units: mmol/mol			
arithmetic mean	61	64	
standard deviation	± 21	± 13	-

End points

End points reporting groups

Reporting group title	Decision support with GlucoTab - Intervention Group

Reporting group description:

Insulin therapy with basal insulin (insulin glargine U300) was started and adjusted according to GlucoTab with incorporated new basal-insulin software algorithm. The goal of the basal-insulin algorithm was to maintain fasting blood glucose within the FBG target according to the predefined health level. After start, basal insulin was administered once daily before breakfast. Insulin dosage prescription was performed according to GlucoTab under supervision of the treating physician. The total daily dose was reduced by 2 units if any BG value was below target and by 4 units if any BG value was ≥ 20 mg/dL below target. The total daily dose was raised according to a titration table. Capillary glucose was measured three times daily before meals at least for the first 3 days of algorithm-based treatment and only once in the morning when therapy was verified to be stable. Correctional bolus insulin was administered according to BG targets in the predefined health status.

Reporting group title	Documentation only in GlucoTab - Control Group

Reporting group description:

Study participants in the control group received standard insulin therapy as judged by the treating physician. This therapy was documented by the health professionals using the GlucoTab system with the feature "custom therapy" without decision support. BG measurements were performed according to the treating physician. To guarantee comparability between treatment and control group at least 3 BG measurements a day for the first three days and later at least FBG values had to be measured.

Primary: The percentage of fasting blood glucose (FBG) values in the FBG target range as calculated by using all FBG values measured ≥ 24 hours after start of therapy

End point title	The percentage of fasting blood glucose (FBG) values in the FBG target range as calculated by using all FBG values measured ≥ 24 hours after start of therapy

End point description:

The percentage of fasting blood glucose (FBG) values in the FBG target range as calculated by using all FBG values measured ≥ 24 hours after start of therapy. The target range depended on the health status of a subject and was defined as follows:
- Tight glycaemic control: 90–130 mg/dL
- Moderate glycaemic control: 90–150 mg/dL

End point type	Primary

End point timeframe:

whole study duration starting >= 24 h after start of therapy

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: Percentage				
arithmetic mean (standard deviation)	58.6 (± 33.2)	51.2 (± 30.8)		

Statistical analyses

Statistical analysis title	efficacy of the basal-insulin algorithm

Statistical analysis description:

Null Hypothesis (H0): Intervention group (basal insulin algorithm) and control group (computerized documentation without decision support) do not differ with respect to the percentage of fasting blood glucose (FBG) values in the FBG target range (as calculated by using all FBG values measured ≥ 24 hours after start of therapy).

Comparison groups	Decision support with GlucoTab - Intervention Group v Documentation only in GlucoTab - Control Group
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0 [2]
Method	bootstrapping
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.938
upper limit	24.534

Notes:

[1] - bootstrapping and confidence interval as result

[2] - The primary endpoint of the study deviates from normality, thus the Intervention Group and Control Group were compared by means of a data-based simulation method (bootstrap method described in the SAP).

Secondary: Overall mean FBG value (pre-breakfast BG)

End point title	Overall mean FBG value (pre-breakfast BG)

End point description:

overall FBG value (pre-breakfast BG)

End point type	Secondary

End point timeframe:

whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: mg/dl				
arithmetic mean (standard deviation)	142 (± 49)	150 (± 38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean daily BG

End point title	Mean daily BG

End point description:

The mean daily BG was calculated for the first three treatment days only, as there were only three daily measurements on these days.

End point type	Secondary

End point timeframe:

first three treatment days

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: mg/dl				
arithmetic mean (standard deviation)	195 (± 74)	201 (± 46)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of BGs below, within or above health dependent target range

End point title	Percentage of BGs below, within or above health dependent target range

End point description:

health dependent target range for tight: 90-130 mg/dl; moderate: 90-150 mg/dl; loose: 100-180 mg/dl

End point type	Secondary

End point timeframe:

whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: Percentage				
number (not applicable)				
BGs below health dependent target range	3.5	0.6		
BGs within health dependent target range	74.8	74.8		
BGs above health dependent target range	21.7	24.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of administered insulin therapy types and concomitant diabetes medication according to treatment days

End point title	Percentage of administered insulin therapy types and concomitant diabetes medication according to treatment days

End point description:

Total number of treatment days in IG were 428, total number of treatment days in control group were 432

End point type	Secondary

End point timeframe:

whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: Percentage				
number (not applicable)				
Basal insulin	74.1	72.2		
Basal insulin plus 1 short acting insulin	15.2	21.3		
Long acting insulin plus > 1 short acting insulin	10.3	1.9		
Premixed insulin	0	4.4		
Short acting insulin only	0.5	0.2		
Concomitant OAD	79.2	77.1		
Concomitant GLP-1	0	5.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of days with BG values below the individual glycaemic target range

End point title	Percentage of days with BG values below the individual glycaemic target range

End point description:
FBG target ranges for tight: 90-130 mg/dl; moderate: 90-150 mg/dl; loose: 100-180 mg/dl

End point type	Secondary

End point timeframe:
whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: Percentage				
number (not applicable)				
days with pre-breakfast BGs below target	5.3	0.4		
days with pre-lunch BG below target	1.8	0.9		
days with pre-dinner BG below target	0.7	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of BG measurements per treatment day

End point title	Number of BG measurements per treatment day

End point description:
number of BG measurements per treatment day based on mean values for each subject

End point type	Secondary

End point timeframe:
whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: number of BG measurements/day				
arithmetic mean (standard deviation)	2.4 (± 0.5)	2.4 (± 0.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Initial insulin dose and insulin end dose

End point title	Initial insulin dose and insulin end dose

End point description:

End point type	Secondary

End point timeframe:
whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: units (IU)				
arithmetic mean (standard deviation)				
initial insulin dose	17 (± 7)	17 (± 6)		
insulin end dose	17 (± 11)	19 (± 8)		
initial basal insulin dose	15 (± 5)	16 (± 5)		
basal insulin end dose	15 (± 8)	18 (± 7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of adherence to GlucoTab suggestions (IG only)

End point title	Percentage of adherence to GlucoTab suggestions (IG only)

End point description:
this endpoint is for IG only since there is no decision support for CG

End point type	Secondary

End point timeframe:
whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: Percentage				
number (not applicable)				

days with compliant BG measurement frequency	88.8	0		
adherence to insulin start dose suggestions	44.4	0		
adherence to suggested basal ins. titration dose	82	0		
adherence to suggested basal ins. injection dose	89.5	0		
adherence to suggested bolus ins. injection dose	65.7	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Subgroup tight glycaemic control: Percentage of BG values in specific ranges according to health dependent target ranges

End point title	Subgroup tight glycaemic control: Percentage of BG values in specific ranges according to health dependent target ranges

End point description:

Percentage of BG values in specific ranges according to health dependent target ranges for tight glycaemic control

End point type	Secondary

End point timeframe:

whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	7		
Units: Percentage of BGs				
number (not applicable)				
0-39 mg/dl	0	0		
40-69 mg/dl	0	0.3		
70-89 mg/dl	4.4	0		
90-130 mg/dl	41.9	22.7		
131-260 mg/dl	51.5	66.1		
261-349 mg/dl	2.2	8.8		
> 349 mg/dl	0	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Subgroup moderate glycaemic control: Percentage of BG values in specific ranges according to health dependent target ranges

End point title	Subgroup moderate glycaemic control: Percentage of BG values in specific ranges according to health dependent target ranges

End point description:

Percentage of BG values in specific ranges according to health dependent target ranges for moderate glycaemic control

End point type	Secondary

End point timeframe:

whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	20		
Units: Percentage				
number (not applicable)				
0-39 mg/dl	0	0		
40-69 mg/dl	0.4	0.1		
70-89 mg/dl	2.9	0.5		
90-150 mg/dl	34.4	38.7		
151-300 mg/dl	52.9	57.3		
301-349 mg/dl	4.1	2.3		
> 349 mg/dl	5.3	1.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of performed, suggested, missed and additional daily BG measurements

End point title	Number of performed, suggested, missed and additional daily BG measurements

End point description:

Number of performed, suggested, missed and additional daily BG measurements per group based on values for each subject and treatment day

End point type	Secondary

End point timeframe:

whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: number of BG measurements				
arithmetic mean (standard deviation)				
Number of performed daily BG measurements	2.5 (± 1.0)	2.4 (± 0.9)		
Number of suggested daily BG measurements	2.1 (± 1.0)	2.4 (± 0.9)		
Number of missed daily BG measurements	0.2 (± 0.5)	0.3 (± 0.6)		
Number of additional daily BG measurements	0.5 (± 0.8)	0.3 (± 0.6)		

Statistical analyses

No statistical analyses for this end point

Secondary: Initial insulin dose and insulin end dose relative to subject weight

End point title	Initial insulin dose and insulin end dose relative to subject weight

End point description:

mean initial insulin dose and mean insulin end dose relative to subject weight

End point type	Secondary

End point timeframe:

whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: IU/kg				
arithmetic mean (standard deviation)				
initial insulin dose (IU/kg)	0.21 (± 0.08)	0.21 (± 0.06)		
insulin end dose (IU/kg)	0.22 (± 0.14)	0.23 (± 0.08)		
initial basal insulin dose (IU/kg)	0.19 (± 0.06)	0.19 (± 0.05)		
basal insulin end dose(IU/kg)	0.20 (± 0.10)	0.23 (± 0.07)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean number of daily insulin injections

End point title	Mean number of daily insulin injections

End point description:

mean number of daily insulin injections per group. A total of 599 (IG) vs. 541 (CG) insulin injections were performed.

End point type	Secondary

End point timeframe:

whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: mean number of insulin injections				
arithmetic mean (standard deviation)				
number of performed insulin injections	1.40 (± 0.77)	1.25 (± 0.48)		
number of insulin injections suggested by GlucoTab	1.22 (± 0.71)	1.23 (± 0.54)		
number of non-performed insulin injections	0.01 (± 0.11)	0.02 (± 0.18)		
number of additional insulin injections	0.18 (± 0.46)	0.04 (± 0.22)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of falls

End point title	Number of falls

End point description:

End point type	Secondary

End point timeframe:

whole study duration

End point values	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	27		
Units: number	3	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 the whole study duration; Time range: 14.06.2017 (FPFV) - 05.10.2018 (LPLV)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23

Reporting groups

Reporting group title	Decision support with GlucoTab - Intervention Group

Reporting group description:

Insulin therapy with basal insulin (insulin glargine U300) was started and adjusted according to GlucoTab with incorporated new basal-insulin software algorithm. The goal of the basal-insulin algorithm was to maintain fasting blood glucose within the FBG target according to the predefined health level. After start, basal insulin was administered once daily before breakfast. Insulin dosage prescription was performed according to GlucoTab under supervision of the treating physician. The total daily dose was reduced by 2 units if any BG value was below target and by 4 units if any BG value was ≥ 20 mg/dL below target. The total daily dose was raised according to a titration table. Capillary glucose was measured three times daily before meals at least for the first 3 days of algorithm-based treatment and only once in the morning when therapy was verified to be stable. Correctional bolus insulin was administered according to BG targets in the predefined health status.

Reporting group title	Documentation only in GlucoTab - Control Group

Reporting group description:

Study participants in the control group received standard insulin therapy as judged by the treating physician. This therapy was documented by the health professionals using the GlucoTab system with the feature “custom therapy” without decision support.

Serious adverse events	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 31 (6.45%)	2 / 27 (7.41%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Musculoskeletal and connective tissue disorders			
Fall causing contusio capitis and contusio occygis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 27 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall causing Fracture Massa lat. sin.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 27 (3.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Fall causing fract. subcap. hum. dext.			
subjects affected / exposed	0 / 31 (0.00%)	1 / 27 (3.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Encephalitis, NINS			
subjects affected / exposed	1 / 31 (3.23%)	0 / 27 (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: 0 %

Non-serious adverse events	Decision support with GlucoTab - Intervention Group	Documentation only in GlucoTab - Control Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 31 (32.26%)	12 / 27 (44.44%)	
Cardiac disorders			
Cardiac decompensation			
subjects affected / exposed	1 / 31 (3.23%)	0 / 27 (0.00%)	
occurrences (all)	1	0	
Collapse			
subjects affected / exposed	0 / 31 (0.00%)	1 / 27 (3.70%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
Nausea	Additional description: Nausea under opiate therapy		
subjects affected / exposed	0 / 31 (0.00%)	1 / 27 (3.70%)	
occurrences (all)	0	1	
Clostridia enteritis			
subjects affected / exposed	0 / 31 (0.00%)	1 / 27 (3.70%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Pneumonia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 27 (0.00%)	
occurrences (all)	1	0	
Respiratory tract infection	Additional description: respiratory tract infection of the upper respiratory tract		

subjects affected / exposed	1 / 31 (3.23%)	0 / 27 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Detoriation of the liver parenchyma			
subjects affected / exposed	0 / 31 (0.00%)	1 / 27 (3.70%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Dermatomycosis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 27 (0.00%)	
occurrences (all)	1	0	
Renal and urinary disorders			
Urinary tract infection			
subjects affected / exposed	2 / 31 (6.45%)	3 / 27 (11.11%)	
occurrences (all)	2	3	
Endocrine disorders			
Hypoglycaemia	Additional description: hypoglycaemia without symptoms		
subjects affected / exposed	2 / 31 (6.45%)	0 / 27 (0.00%)	
occurrences (all)	2	0	
Musculoskeletal and connective tissue disorders			
Fall			
subjects affected / exposed	2 / 31 (6.45%)	4 / 27 (14.81%)	
occurrences (all)	2	4	
Gout arthritis			
subjects affected / exposed	0 / 31 (0.00%)	1 / 27 (3.70%)	
occurrences (all)	0	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.

similarity of both groups was not taken into account in the power calculation; less patients than calculated in the sample size calculation were included in the study; no patients with health status "loose" glycaemic control were included;

Notes: