



Clinical trial results:

Effects of continuous exercise on time spent in euglycemia and inflammation under the treatment of insulin degludec in patients with type 1 diabetes – a crossover, randomized trial (InflamEx)

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2017-000922-37 |
| Trial protocol | AT |
| Global end of trial date | 16 May 2018 |

Results information

| | |
|--------------------------------|-----------------|
| Result version number | v1 (current) |
| This version publication date | 05 January 2024 |
| First version publication date | 05 January 2024 |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | InflamEX |
|-----------------------|----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Medical University of Graz |
| Sponsor organisation address | Neue Stiftingtalstrasse 6, Graz, Austria, |
| Public contact | Harald Kojzar (Project Coordinator), Medical University of Graz, harald.kojzar@medunigraz.at |
| Scientific contact | Prof. Dr. Harald Sourij (Principal Investigator), Medical University of Graz, ha.sourij@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 | 26 April 2018 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 26 April 2018 |
| Global end of trial reached? | Yes |
| Global end of trial date | 16 May 2018 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Difference in mean time in euglycemia 24 hours after exercise

Protection of trial subjects:

ethical standards were followed, the trial adhere to strict ethical standards to ensure that participants were treated fairly and with respect protecting the privacy and confidentiality of participants education and training in protection of clinical trials participants for all study team members

Background therapy: -

Evidence for comparator: -

| | |
|---|-------------------|
| Actual start date of recruitment | 18 September 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: 10 |
| Worldwide total number of subjects | 10 |
| EEA total number of subjects | 10 |

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) | 10 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Study participants were recruited using the subject database of our department

Pre-assignment

Screening details:

- Informed consent
- Inclusion/Exclusion criteria
- Demography
- Participants diabetes history, current insulin therapy
- Medical history, concomitant illness
- Body measurements and vital signs
- ECG
- HbA1c measurement

Period 1

| | |
|------------------------------|----------------|
| Period 1 title | Baseline |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|--|------------------|
| Arm title | Baseline |
| Arm description: - | |
| Arm type | Baseline |
| Investigational medicinal product name | Insulin Degludec |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Injection |

Dosage and administration details:

Insulin Degludec administrated according to the investigator

| | |
|---------------------------------------|----------|
| Number of subjects in period 1 | Baseline |
| Started | 10 |
| Completed | 10 |

Period 2

| | |
|------------------------------|-------------------------|
| Period 2 title | Intervention period |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Arms

| | |
|------------------------------|--------------|
| Are arms mutually exclusive? | Yes |
| Arm title | 100% Degudec |

Arm description: -

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Insulin Degludec |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Injection |

Dosage and administration details:

Insulin Degludec 100% as told by the investigator

| | |
|------------------|--------------|
| Arm title | 75% Degludec |
|------------------|--------------|

Arm description: -

| | |
|--|-------------------|
| Arm type | Active comparator |
| Investigational medicinal product name | Insulin Degludec |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Injection |

Dosage and administration details:

Insulin Degludec 75% as told by the investigator

| Number of subjects in period 2 | 100% Degudec | 75% Degludec |
|---------------------------------------|--------------|--------------|
| Started | 5 | 5 |
| Completed | 5 | 4 |
| Not completed | 0 | 1 |
| Consent withdrawn by subject | - | 1 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|----------|
| Reporting group title | Baseline |
|-----------------------|----------|

Reporting group description: -

| Reporting group values | Baseline | Total | |
|---|----------|-------|--|
| Number of subjects | 10 | 10 | |
| 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) | 10 | 10 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous | | | |
| Units: years | | | |
| arithmetic mean | 32.1 | | |
| standard deviation | ± 9.0 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 4 | 4 | |
| Male | 6 | 6 | |

End points

End points reporting groups

| | |
|--------------------------------|--------------|
| Reporting group title | Baseline |
| Reporting group description: - | |
| Reporting group title | 100% Degudec |
| Reporting group description: - | |
| Reporting group title | 75% Degludec |
| Reporting group description: - | |

Primary: Difference in mean time in euglycemia 24 hours after exercise

| | |
|----------------------------|---|
| End point title | Difference in mean time in euglycemia 24 hours after exercise |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| 2 weeks (1 week per group) | |

| End point values | 100% Degudec | 75% Degludec | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 5 | 4 | | |
| Units: hours | | | | |
| arithmetic mean (standard deviation) | 57 (\pm 14) | 62 (\pm 15) | | |

Statistical analyses

| | |
|---|-----------------------------|
| Statistical analysis title | Crossover Trial Analysis |
| Comparison groups | 100% Degudec v 75% Degludec |
| Number of subjects included in analysis | 9 |
| Analysis specification | Pre-specified |
| Analysis type | other |
| P-value | = 0.04 |
| Method | ANOVA |

Secondary: Numbers of confirmed hypoglycemic episodes during exercise (< 4.4 mmol/l

| | |
|------------------------|--|
| End point title | Numbers of confirmed hypoglycemic episodes during exercise (< 4.4 mmol/l |
| End point description: | |
| End point type | Secondary |

End point timeframe:

2 tweeks of training during the one hour exercise per day

| | | | | |
|--|-----------------|-----------------|--|--|
| End point values | 100% Degudec | 75% Degludec | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 5 | 4 | | |
| Units: Hypo´s (blood sugar below 4,4 mmol/l) | 0 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse event date was collected from 25.Oct.2017 (first patient first visit) until 02.Mar.2018 (last patient last visit).

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 26.0 |

Reporting groups

| | |
|-----------------------|--------------|
| Reporting group title | 75% Degludec |
|-----------------------|--------------|

Reporting group description: -

| Serious adverse events | 75% Degludec | | |
|---|---------------|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 1 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

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

| Non-serious adverse events | 75% Degludec | | |
|---|-----------------|--|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | | |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 1 / 1 (100.00%) | | |
| 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

None reported