A multicenter, multinational, prospective, interventional, single-arm, Phase IV study evaluating the clinical efficacy and safety of 26 weeks of treatment with insulin glargine 300 U/mL (Gla-300) in patients with Type 2 diabetes mellitus uncontrolled on basal insulin

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Main Information

Primary registry identifying number
LBCTR2019040212

Protocol number
LPS15396

MOH registration number
14926/2/2019

Study registered at the country of origin
No

Study registered at the country of origin: Specify
Study not registered at the Country of origin .France is not a participating country

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency
15/03/2019

Primary sponsor
Sanofi

Primary sponsor: Country of origin
France

Date of registration in primary registry
11/04/2019

Date of registration in national regulatory agency
15/03/2019

Public title
A multicenter, multinational, prospective, interventional, single-arm, Phase IV study evaluating the clinical efficacy and safety of 26 weeks of treatment with insulin glargine 300 U/mL (Gla-300) in patients with Type 2 diabetes mellitus uncontrolled on basal insulin

Acronym
ARTEMIS-DM

Scientific title
A multicenter, multinational, prospective, interventional, single-arm, Phase IV study evaluating the clinical efficacy and safety of 26 weeks of treatment with insulin glargine 300 U/mL (Gla-300) in patients with Type 2 diabetes mellitus uncontrolled on basal insulin

Acronym
ARTEMIS-DM

Brief summary of the study: English

STUDY NAME: ARTEMIS
STUDY NUMBER: LPS15396
STUDY SPONSOR : Sanofi Aventis Groupe
Investigational product :TOUJEO® (Insulin glargine 300 units/mL)
INVESTIGATORs:
Dr Maya Chehabeddine
Dr Hussam Ghosn

-What is the purpose of the study?
Diabetes mellitus is an illness where the body does not respond well enough to his own insulin or it does not produce enough insulin to control his blood sugar.
The study drug Insulin glargine 300 units/mL (Gla-300), referred throughout the document as the "study drug". It is a modified insulin, very similar to human insulin. Gla-300 is provided in a prefilled pen for subcutaneous (under the skin) injection. Gla-300 contains 3 times more insulin in 1 ml than standard insulin (Gla-100), which contains 100 units/ml.
Gla-300 lowers the blood sugar steadily over a long period of time. It is used for once daily dosing.
The purpose of this study is to find out how well Gla-300 works for patients with type 2 diabetes mellitus (T2DM) in a wide geographic setting, among population of various ethnic backgrounds and different lifestyles, and how safe it is. In addition, the study aims to evaluate patient satisfaction including convenience of the study intervention, blood glucose control, hypoglycaemia (low blood sugar) control, and convenience and satisfaction with the device.
-Expenses and payment
The participation is free of charge. The patient will be provided with the study drug, examinations and medical care related to the study at no cost.
Patient will only be reimbursed for travel expenses to participate in this study,
-What will happen if the patient take part in this study?
The patient has been asked to participate in this trial because he is at least 18 years old and has T2DM.
The study will comprise 3 periods:
• A screening period of up to 2 weeks
• A 26-week treatment period
• A post-treatment follow-up phone call visit at Week 27
-What could be the side effects of the study drug and of study procedures?
• Hypoglycemia: In case of hypoglycemia or low blood sugar patient may feel the following symptoms: sweating, rapid heartbeat, hunger, tremor (shaking), fatigue, headache, restlessness, anxiety, irritability, mood change, trouble concentrating, blurred vision, dizziness, light-headedness or drowsiness and, in worst cases, fainting or unconsciousness.
• Injection Site Reactions: such as reddening, unusually intense pain on injection, itching, hives, swelling or inflammation.
• Allergic Reactions: Symptoms of allergy can include a rash over all the body, itching, and shortness of breath, wheezing (trouble breathing), a fast pulse, sweating or low blood pressure.
• Vision Changes: A marked change (improvement or worsening) in the blood sugar control can disturb the vision temporarily.
• Water Retention: In rare cases, insulin treatment may also cause temporary build-up of water in the body, with swelling in the calves and ankles.
• Very Rare Symptoms: taste disorders and muscular pain can occur.
-Study information
A description of this study will be available on https://clinicaltrials.gov. This website will not include information that can identify the patient.
-Study results
When this study is completed, a simple summary of the overall results will be prepared for the general public.

Brief summary of the study: Arabic

اسم الدراسة: ARTEMIS
رقم الدراسة: LPS15396
راعي الدراسة: مجموعة سانوفي أفنتيس
دواء الدراسة : TOUJEO® إنسولين غلارجين، 300وحدة/مل
الباحث: الدكتور حسام غصن
الباحث: الدكتور مايا شهاب الدين

ما الغرض من الدراسة؟

السُكري هو مرض لا يستجيب الجسم فيه كافية للإنسولين الخاص به أو لا يُفرز الجسم كمية كافية من الإنسولين للتحكّم في مُعدل السكر في الدم. المُشار إليه في هذا المستند من أوله لآخره بلفظ "دواء الدراسة". وهو إنسولين (Gla-300) وحدة/مل300أما دواء الدراسة، إنسولين غلارجين (Gla-300) من1في قلم سابق التعبئة للحقن تحت الجلد. ويحتوي المليلتر الواحد (Gla-300 مُعدَّل، يماثل الإنسولين البشري بدرجة كبيرة جدًا. يُقدَّم 300 وحدة/مل. ويُخفض100الذي يحتوي على (Gla-100) على ثلاثة أضعاف كمية الإنسولين الموجودة في نظيره في الإنسولين المعياري كمية السُكر في الدم على مدار فترة زمنية طويلة. ويُستخدم بجرعة مرة واحدة يوميًا Gla-300.
في مكان جغرافي (T2DM) 2لدى المرضى المصابين بالسُكري من النوع Gla-300 الغرض من هذه الدراسة اكتشاف مدى فعالية وسلامة ،واسع بين فئة تضم أُناس ذوي خلفيات عرقية متنوعة يعيشون بأساليب حياة مختلفة. وبالإضافة إلى ذلك، تهدف الدراسة إلى تقييم رضا المرضى بما في ذلك مُلاءَمَة التدخُل في الدراسة والتحكّم في مستوى الغلوكوز في الدم ونقص غلوكوز الدم (انخفاض السُكر في الدم)، وراحة المرضى مع الجهاز ورضاهم عنه.

النفقات والدفع
المشاركة سوف تكون مجانًا. سيُقدَّم للمريض دواء الدراسة والفحوصات والرعاية الطبية المتعلقة بالدراسة دون أي تكلفة عليه.

لن يُقدَّم له تعويض إلا تعويضًا عن مصاريف السفر للمشاركة في الدراسة.

ماذا سيحدث إذا شارك المريض في هذه الدراسة؟

طُلِبَ من المريض المشاركة في هذه التجربة لأن عُمره لا يقل عن 18 عامًا ويعاني من مرض السُكري من النوع 2 (T2DM).
تتكون الدراسة من3 فترات:
- فترة الفرز وتستمر حتى أسبوعين
- فترة العلاج وتتكون من 26أسبوعًا
- زيارة تُنسَّق بمكالمة هاتفية في فترة المتابعة بعد العلاج، في الأسبوع 27

ما الآثار الجانبية المحتملة لدواء الدراسة وإجراءاتها؟

- نقص جلوكوز الدم: في حالة نقص جلوكوز الدم أو انخفاض السُكر في الدم، ربما يشعر المريض بالأعراض التالية: التعرُق، أو تسارُع نبض القلب، أو الجوع، أو الرُعاش (هزة)، او إرهاق، أو صُداع، أو تَمَلْمُل، أو قلق، أو هَيوجيَّة، أو تغيرات مزاجية، أو مشكلة في التركيز، أو تشوش الرؤية، أو الدوخة، أو الدوار، أو النعاس، وفي أسوأ الحالات، يحدث إغماء أو فقد الوعي. وإذا اشتدت الحالة، قد تحدث للمريض نوبات مَرَضية أو غَيْبُوبَة،أو فقد الوعي.
- تفاعلات في موضع الحقن: مثل الاحمرار، أو الألم الشديد لدرجة غير اعتيادية، أو الحكة، أو الشَرَى، أو التورُم، أو الالتهاب.
- ردود فعل تحسسية: وتشمل أعراض الحساسية: الطفح الجلدي، أو الحكة، أو ضيقُ النَّفس، أو صَفِيرٌ عِنْدَ التَّنَفُّس (مشكلة في التنفس)، أو تسارع نبض القلب، أو التعرُق، أو انخفاض ضغط الدم.
- تغيرات الرؤية: قد يتسبب التغيير الملحوظ في التحكّم في السكر في دم المريض (سواء أكان تحسنًا أو سوءًا) في تغير الرؤية مؤقتًا.
- احتباس المياه: في حالات نادرة، قد يُسبب العلاج بالإنسولين إضافة إلى ذلك تراكُم مؤقت للمياه في الجسم، مع إصابة ربلات الرجل والكواحل بتورُم.
- أعراض نادرة جدًا: في حالات نادرة جدًا، ربما تحدث اضطرابات في التذوق وألم عضلي.

معلومات عن الدراسة

لن يتضمن هذا الموقع أي معلومات يمكنها أن تحدد هُوية المريض. https://clinicaltrials.gov يتوفر وصف لهذه الدراسة على هذا الموقع الإلكتروني.

نتائج الدراسة

عند اكتمال هذه الدراسة، سيُعَد لعامة الناس مُلخَص بسيط للنتائج الإجمالية.

Health conditions/problem studied: Specify

Patients with Type 2 diabetes mellitus uncontrolled on basal insulin

Interventions: Specify

- Study intervention name: Insulin glargin
Dosage formulation: Gla-300 will be supplied as a sterile, non-pyrogenic, clear, colorless solution in SoloStar® prefilled (disposable) pen for SC injection. SoloStar pen is necessary for Gla-300 administration and it is considered as integral part of the IMP.
Unit dose strength(s)/Dosage level(s): Each SoloStar pen contains total of 450 Units of insulin glargine (1.5 mL of 300 Units/mL insulin glargine solution). The pen allows dose setting in the range 1-80 units.
Route of administration: SC self-injection
Dosing instructions: Gla-300 will be self-injected SC once daily at any time of the day. The clock time for the injection (hh:mm) will be established at the discretion of the participant/Investigator at baseline and will be maintained for the duration of the study. The insulin dose will be adjusted according to the recommend titration algorithm.
Packaging and labeling: Study intervention will be provided at the site in SoloStar pen. Each SoloStar pen and box will be labeled as required per country requirement.
The participants will be trained on self-injection of IMP using SoloStar pen at baseline and will be repeated during the study, if necessary. The SoloStar pen handling procedure (Instruction for Use) and injection techniques are provided in the Study Reference Manual and will also be provided to the participants.
- Non-investigational Medicinal Product(s)

Background non-insulin antidiabetic drug(s) administered at stable dose for at least 8 weeks prior to screening will be continued during the treatment period except if they have to be stopped or adapted for safety reasons.
Formulation and route(s) of administration of antidiabetic background therapy will be as per the local labeling.
- Devices
Each patient will be provided with a blood glucose meter (Accu-Chek Performa®) supplied by the sponsor at visit 1 and will be instructed in its use.
The blood glucose meter will be provided with lancing-device, test strips, sterile lancets, storage box, control solution, and instruction for use.
At each visit, the patient will be given at least the quantity of test strips and lancets required until the following visit.
Strict blood glucose self-monitoring is necessary to achieve the blood glucose targets for the study. The patient will be encouraged to conduct daily self-monitored blood glucose assessment.

Key inclusion and exclusion criteria: Inclusion criteria

Protocol: Page 26-27
Participants are eligible to be included in the study only if all of the following criteria apply:
-Age:
I 01. Participants must be >18 years of age (inclusive), at the time of signing the informed consent.
-Type of participant and disease characteristics
I 02. Participants with T2DM.
I 03. Participants on “standard of care” basal insulin therapy (including Gla-100, detemir, degludec, NPH insulin), administered once or twice daily, as per labeling for at least 6 months prior to screening visit, with or without oral agents (metformin, sulfonylurea, thiazolidinedione, DPP-4 inhibitor, SGLT-2 inhibitor, glinide, α-glucosidase inhibitor) and with or without use of a GLP-1 receptor agonist, approved for using with insulin.
I 04. HbA1c between 7.5% (58 mmol/mol) and 10% (86 mmol/mol) inclusive, during screening.
I 05. Median of the last 3 consecutive fasting SMPG values prior to baseline, or at least 2 fasting SMPG values in the week prior to baseline >130 mg/dL.
-Sex
I 06. Male or Female
- Female participants: A female participant is eligible to participate if she is not pregnant not breastfeeding, and at least 1 of the following conditions applies:
- Not a woman of childbearing potential (WOCBP) as defined in Appendix 4 (Section 10.4).
OR
- A WOCBP who agrees to follow the contraceptive guidance in Appendix 4 (Section 10.4) during the intervention period and for at least 1 week after the last dose of study intervention (ie, until Week 27).
-Informed Consent
I 07. Capable of giving signed informed consent as described in Appendix 1 (Section 10.1.3) which includes compliance with the requirements and restrictions listed in the informed consent form (ICF) and in this protocol.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

90

Key inclusion and exclusion criteria: Exclusion criteria

Participants are excluded from the study if any of the following criteria apply:
-Medical conditions
E 01. Any clinically significant abnormality identified either in medical history or during screening evaluation (eg, physical examination, laboratory tests, electrocardiogram, vital signs) or any AEs during screening period which in judgment of the Investigator would preclude safe completion of the study or constrains efficacy assessment.
E 02. Known presence of factors that interfere with the HbA1c measurement (eg, specific hemoglobin variants, hemolytic anemia) compromising the reliability of HbA1c assessment or medical conditions that affect interpretation of HbA1c results (eg, blood transfusion or severe blood loss in the last 3 months prior to baseline, any condition that shortens erythrocyte survival).
E 03. History of severe hypoglycemia requiring emergency room admission or hospitalization within 3 months prior to screening visit.
E 04. Proliferative retinopathy or maculopathy requiring treatment according to the Investigator.
-Prior/concomitant therapy
E 05. Unstable basal insulin regimen in the last 8 weeks prior to screening visit (ie, type of insulin and time/frequency of the injection, insulin doses [variation more than ±20%]).
E 06. Treatment with insulin other than basal insulin: mixed insulin (premixes), rapid insulin, and fast acting insulin analogues in the last 6 months before screening visit (use ≤10 days in relation to hospitalization or an acute illness is accepted).

E 07. Use of non-insulin antidiabetic drugs other than those listed in inclusion criteria.
E 08. Change in existing dose or initiation of new, non-insulin antidiabetic drugs in the 8 weeks prior to screening visit.
E 09. Use of systemic glucocorticoids (excluding topical application or inhaled forms) for
2 weeks or more within 8 weeks prior to screening visit.
E 10. Likelihood to require treatment prohibited by the protocol during the study.
-Prior/concurrent clinical study experience
E 11. Exposure to any investigational drugs in the last 4 weeks or 5 half-lives, whichever is longer, prior to screening visit or concomitant enrollment in any other clinical study
involving an investigational study treatment.
-Diagnostic Assessments
Not applicable
- Other exclusions
E 12. Any specific situation during study implementation/course that may raise ethics considerations.
E 13. History of hypoglycemia unawareness.
E 14. Known hypersensitivity/intolerance to Gla-300 or any IMP excipients.
E 15. History of drug or alcohol abuse within 6 months prior to screening visit.
-Additional criteria at the end of the screening period
E 16. Participants unwilling or unable to comply with study procedures as outlined in the protocol.
E 17. Participants who withdraw consent during the screening (starting from signed ICF).

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

N/A: Single arm study

Study design: Masking

Open (masking not used)

Study design: Control

Uncontrolled

Study phase

4

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Germany-etc

Name of IMP

Insuline glargine - The medication Toujeo will be purchased locally (297 Boxes) from the market and will be labelled on the secondary Packaging: please refer to the Pharmaceutical class for the local labeling.

Year of authorization

2016

Month of authorization

3

Type of IMP

Others

Pharmaceutical class

Basal Insulin -(Insulin glargine 300 units/ml) marketed as Toujeo in most countries.

- Labeling to be affixed at the secondary packaging:

Artemis study
LPS15396
اسم المركز: ----------
اسم الباحث: الدكتور ----------
Toujeo®
دواء البحث- للاستعمال في البحث السريري فقط.
تعاد الأقلام المستعملة أو غير المستعملة في علبتها الى المركز
------- --------- رقم المريض:
رقم العلبة : -------
رقم الزيارة : ----------
تاريخ تسليم الدواء:----------
تاريخ اعادة الدواء الى المركز: ----------

Therapeutic indication

Treatment of diabetes mellitus in adults.

Therapeutic benefit

Following subcutaneous (SC) injection, Gla-300 has been shown to have smoother, more stable, and prolonged pharmacokinetic and pharmacodynamic profiles than insulin glargine 100 units/mL (Gla-100), resulting from a more gradual and extended release of glargine from the SC depot.
Based on these properties, Gla-300 demonstrated a low risk for nocturnal hypoglycemic events in its clinical trial program. Concurrently, Phase III studies have provided evidence for a non-inferior glucose lowering effect when compared to Gla-100.

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

NA

Target sample size

11

Actual enrollment target size

Date of first enrollment: Type

Anticipated

Date of first enrollment: Date

01/04/2019

Date of study closure: Type

Anticipated

Date of study closure: Date

30/06/2020

Recruitment status

Other

Recruitment status: Specify

Recruitment is not started yet. Study initiation is planned on Mar 29th, 2019.

Date of completion

IPD sharing statement plan

No

IPD sharing statement description

All personal data collected related to participants, Investigators, or any person involved in the study, which may be included in the Sponsor's databases, shall be treated in compliance with all applicable laws and regulations including the GDPR (Global Data Protection Regulation).
Participants will be assigned a unique identifier by the Sponsor. Any participant records or datasets that are transferred to the Sponsor will contain the identifier only; participant names or any information which would make the participant identifiable will not be transferred.(protocol-page 54)

Additional data URL

NA

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
UTN Number	U1111-1203-8663

Sources of Monetary or Material Support

Name
Sanofi-France

Secondary Sponsors

Name
CRO: IQVIA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Husam Ghusn	Ain Wazein-Chouf	Lebanon	05-509001	husam.ghusn@awh.org.lb	Ain Wazein village Hospital
Scientific	Bejjani Guilda	Corniche El Nahr-Pierre Gemayel street- Holcom Bldg-2nd floor-Sanofi	Lebanon	03-178081	guilda.bejjani@sanofi.com	Sanofi Liban
Public	Maya Chehabeddine	Jnah -Beirut	Lebanon	03-821367	mayach_77@hotmail.com	rafic Hariri University Hospital

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Ain Wazein Hospital	Dr Hussam Ghosn	Endocrinologist	Approved
Rafic Hariri University Hospital	Dr Maya Chehabeddine	Endocrinologist	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Ain w Zein Medical Village	25/01/2019	Dr Khaled Abdel Baki	irb@awmedicalvillage.org	+961 (5) 509 001
Rafic Hariri University Hospital	26/02/2019	Dr Iyad Issa	iyadissa71@gmail.com	+961 (3)260908

Countries of Recruitment

Name
Lebanon
Egypt
Colombia
India
Indonesia
Peru
South Africa

Health Conditions or Problems Studied

Condition	Code	Keyword
Diabetes Mellitus	Disease of intestine, unspecified (K63.9)	Diabetes

Interventions

Intervention	Description	Keyword
Investigational Medicinal Product	Insulin glargine 300 UI/ml	basal insulin
Devices	blood glucose meter (Accu-Chek Performa®) supplied by the sponsor at visit 1 and patient will be instructed in its use	glucosemeter

Primary Outcomes

Name	Time Points	Measure
HbA1c	baseline to Week 26	Change in HbA1c

Key Secondary Outcomes

Name	Time Points	Measure
effects of Gla-300 on glycemic control: HbA1c	baseline to Week 12	Change in HbA1c
effects of Gla-300 on glycemic control: HbA1c<7%	at Weeks 12 and 26.	Percentage of participants
effects of Gla-300 on glycemic control:self-monitored plasma glucose (SMPG) of 80 to 110 mg/dL	at Weeks 12 and 26	Percentage of participants
effects of Gla-300 on glycemic control: fasting plasma glucose (FPG)	baseline to Week 26	Change in fasting plasma glucose
effects of Gla-300 on glycemic control: fasting SMPG	baseline to Week 26.	Change in fasting SMPG
effects of Gla-300 on glycemic control: 7-point SMPG profile	baseline to Week 26	Change from baseline to Week 26
effects of Gla-300 on glycemic control: Rescue therapy	by Weeks 12 and 26	Percentage of participants
Safety Gla -300:at least 1 hypoglycemia	from baseline to Week 26.	Number of participants
Safety Gla-300: adverse events (AEs) and serious adverse events (SAEs)	from baseline to Week 26.	Number of participants
effects of Gla-300 on treatment satisfaction	from baseline to Week 26.	Change in treatment satisfaction as measured by insulin treatment satisfaction questionnaire (ITSQ)
effects of Gla-300 on healthcare resource	from baseline to Week 26	Number of participants with HCRU (hospitalization,

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files