

Prevention of bleeding in haemophilia A by prophylactic treatment with Nuwq®

Submission date 23/02/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/03/2015	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/06/2025	Condition category Haematological Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Haemophilia A is an inherited condition where there's not enough of a substance called clotting factor VIII in the blood as there should be, so the patient bleeds for longer than usual.

Octanate® and Wilate® are human plasma-derived factor VIII concentrate, and Nuwq® is an engineered version of clotting factor VIII. The aim of this study is to find out whether treatment with Octanate®, Wilate® or Nuwq prevents bleeding in patients with haemophilia A.

Who can participate?

Haemophilia A patients being treated with Octanate®, Wilate® or Nuwq®

What does the study involve?

The routine treatment of haemophilia A patients is documented, including all treatments with Nuwq, any bleeding episodes, surgical procedures, and quality of life.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Vivantes Klinikum (Germany)

When is the study starting and how long is it expected to run for?

March 2015 to March 2030

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Jennifer Feddern

Contact information

Type(s)

Scientific

Contact name

Ms Angela Habier

Contact details

Elisabeth-Selbert-Strasse 11
Langenfeld
Germany
40764

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

GENA-100

Study information

Scientific Title

Prevention and treatment of bleeding in haemophilia A with Nuwiiq®: Octanate®, Wilate®: A prospective, non-interventional study to evaluate prophylactic and on-demand treatment schedules and factor VIII requirement in routine clinical practice

Acronym

PEAQ-NOW

Study objectives

To assess the influence of weekly FVII dose on annualized bleeding rate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Medical Association Berlin, 18/11/2015, ref: Eth-11/15

Study design

Open prospective multi-centre multi-national non-interventional study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Haemophilia A

Interventions

Current interventions as of 19/03/2024:

NIS-Previq is a non-interventional study for which the routine treatment of haemophilia A patients on prophylaxis is documented. All treatments with Octanate®, Wilate® or Nuwiq®, any bleeding episode occurring or surgical procedures are carefully documented. Additionally, a joint score (HJHS) and/or a pharmacokinetic evaluation with individually calculated dosing schedules can be documented on an optional basis.

Previous interventions:

NIS-Previq is a non-interventional study for which the routine treatment of haemophilia A patients on prophylaxis is documented. All treatments with Nuwiq, any bleeding episode occurring or surgical procedures are carefully documented. Additionally, a joint score (HJHS), quality of life questionnaire (SF-36) and/or a pharmacokinetic evaluation with individually calculated dosing schedules can be documented on an optional basis.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Simoctocog alfa, Octanate®, Wilate®

Primary outcome measure

Current primary outcome measure as of 19/03/2024:

Annual bleeding rate (ABR) during prophylaxis with Octanate®, Wilate® or Nuwiq® and ABR by weekly Nuwiq doses (IU/kg)

Previous primary outcome measure:

Annual bleeding rate (ABR) during prophylaxis with Nuwiq and ABR by weekly Nuwiq doses (IU/kg)

Secondary outcome measures

Current secondary outcome measures as of 19/03/2024:

1. Frequency distribution of the infusion intervals used – e.g. once, twice, thrice weekly or more frequently.

1.1. FVIII Dose/kg body weight per injection

- 1.2. Weekly FVIII Dose/kg body weight
2. Changes in HJHS Score results over time and after PK-based adjustments of prophylactic schedule.
3. Efficacy assessments for treatment of bleeding episodes according to a 4-point verbal rating scale
4. ADR rates per infusion and per patient

Previous secondary outcome measures:

1. Frequency distribution of the infusion intervals used – e.g. once, twice, thrice weekly or more frequently.
- 1.1. FVIII Dose/kg body weight per injection
- 1.2. Weekly FVIII Dose/kg body weight
2. Changes in SF-36 results over time and after PK-based adjustments of prophylactic schedule.
3. Changes in HJHS Score results over time and after PK-based adjustments of prophylactic schedule.
4. Efficacy assessments for treatment of bleeding episodes according to a 4-point verbal rating scale
5. ADR rates per infusion and per patient

Overall study start date

01/03/2015

Completion date

31/03/2030

Eligibility

Key inclusion criteria

Current inclusion criteria as of 11/06/2025:

1. The patient suffers from haemophilia A or reduced factor VIII levels with bleeding tendency
2. Treated with Octanate®, Wilate® or Nuwiq®
3. One of the following criteria is met:
 - 3.1. The Patient receives prophylaxis with FVIII and a duration of 6 month is foreseen
 - 3.2. The Patient is treated on demand with FVIII and treatment within the next 6 month is likely
 - 3.3. The Patient receives prophylaxis with non-factor preparation and is in actual need of factor VIII treatment
4. Good compliance regarding documentation of FVIII treatments and bleeding episodes (in case home treatment is performed)

Previous inclusion criteria as of 19/03/2024:

1. Haemophilia A
 2. Treated with Octanate®, Wilate® or Nuwiq®
 3. Prophylactic treatment schedule for at least 6 months is to be expected
 4. Good compliance regarding documentation of FVIII treatments and bleeding episodes (in case home treatment is performed)
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Previous inclusion criteria:

1. Haemophilia A
2. Treated with Nuwiq
3. Prophylactic treatment schedule for at least 6 months is to be expected
4. Good compliance regarding documentation of FVIII treatments and bleeding episodes (in case home treatment is performed)

Participant type(s)

Patient

Age group

All

Sex

Both

Target number of participants

200

Key exclusion criteria

Patients with known contraindications as specified in the SPC

Date of first enrolment

01/03/2015

Date of final enrolment

31/08/2024

Locations

Countries of recruitment

Germany

Study participating centre

Vivantes Klinikum Friedrichshain

Landsberger Allee 49

Berlin

Germany

10249

Sponsor information

Organisation

Octapharma GmbH

Sponsor details

Elisabeth-Selbert-Strasse 11
Langenfeld
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40764

Sponsor type

Industry

ROR

<https://ror.org/002k5fe57>

Funder(s)**Funder type**

Not defined

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Publication plans for the current study are not defined and will be made available at a later date

Intention to publish date

28/02/2026

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date