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

Submission date	Recruitment status	[ ] Prospectively registered
23/02/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/03/2015	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/06/2025	Haematological Disorders	[X] 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 Nuwiq® is an engineered version of clotting factor VIII. The aim of this study is to find out whether treatment with Octanate®, Wilate® or Nuwiq prevents bleeding in patients with haemophilia A.

Who can participate?
Haemophilia A patients being treated with Octanate®, Wilate® or Nuwiq®

What does the study involve?
The routine treatment of haemophilia A patients is documented, including all treatments with Nuwiq, 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
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40764

Additional identifiers

Protocol serial number
GENA-100

Study information

Scientific Title
Prevention and treatment of bleeding in haemophilia A with Nuwiq®: 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

Study type(s)
Treatment

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 occuring 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 occuring 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(s)
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)

Key secondary outcome(s))
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

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)

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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

Healthy volunteers allowed
No

Age group
All

Sex

All

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

ROR
https://ror.org/002k5fe57

Funder(s)

Funder type
Not defined

Funder Name
Investigator initiated and funded

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes