A Phase 2 randomized, placebo-controlled, double-masked proof-of-concept study to investigate the efficacy and safety of runcaciguat (BAY 1101042) in patients with moderately severe to severe non-proliferative diabetic retinopathy.

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This Phase 2 study is conducted to investigate the safety and efficacy of runcaciguat in the treatment of diabetic retinopathy. The study comprises two subparts, 1 (PK/PD) and 2 (proof of concept); both subparts will be conducted in parallel. To…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Interventional

Summary

ID

NL-OMON54177

Source
ToetsingOnline

Brief title
NEON-NPDR

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
leakage of fluid and blood from blood vessels in the retina, non-proliferative diabetic

retinopaty

Research involving
Human

Sponsors and support

Primary sponsor: Bayer
Source(s) of monetary or material Support: Bayer AG

Intervention

Keyword: Diabetic Retinopathy, Runcaciguat

Outcome measures

Primary outcome

Primary Outcome Measures:

• DRSS improvement >=2 steps at 48 Weeks of treatment in the study eye

DRSS (Diabetic Retinopathy Severity Scale) will be graded centrally.

Secondary outcome

Secondary Outcome Measures:

• Vision threatening complications at 48 weeks of treatment in the study eye

• DRSS improvement >=2 steps at 24 Weeks of treatment in the study eye

• Frequency of treatment emergent adverse events

Study description

Background summary

Proof-of-concept study to investigate the efficacy and safety of runcaciguat (BAY 1101042) in patients with moderately severe to severe non-proliferative diabetic retinopathy.

Study objective

This Phase 2 study is conducted to investigate the safety and efficacy of

runcaciguat in the treatment of diabetic retinopathy. The study comprises two subparts, 1 (PK/PD) and 2 (proof of concept); both subparts will be conducted in parallel. To assess the efficacy, the retinal morphology will be investigated by 7-field color fundus photography (CFP) supported by 7 Field FA images for the assessment of the DRSS by a central reading center. Two-step DRSS improvement at 48 weeks of treatment will be the primary efficacy endpoint. DRSS assessment will continue until the end of the 48-week treatment period. In addition, vision-threatening complications will be recorded throughout the study and assessed as secondary efficacy endpoint.

Study design

Multicenter, randomized, double-masked, parallel-group, placebo-controlled study.

Intervention

Runcaciguat is being compared to placebo.

Study burden and risks

More information on the safety as well as burden and risks is available in the PIIC and the IB.
In addition there could be potential side effects or potential burden due to the procedures done in this study.
If the burden and risks are perceived as disadvantageous for the patient, the patient can always stop the study without giving any reason and without experiencing any consequences for medical care.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Moderately severe to severe NPDR in the study eye: DRSS levels 47 or 53
- Diabetes type 1 or 2
- BCVA ETDRS letter score in the study eye of >=69 letters (approximate Snellen equivalent of 20/40 or better)

Exclusion criteria

- Presence or history of macular edema involving the center of the macula (defined as the area of the center subfield on OCT) in the study eye with visual impairment or in need of treatment with anti-VEGF, immediately or anticipated within the next 3 months, by judgement of the investigator or with OCT central subfield thickness above gender specific thresholds, measured including Bruch*s membrane, >=305 µm in women, >= 320 µm in men, as provided by the central reading center
- Any kind of neovascular growth in the study eye, including anterior segment neovascularization
- Arterial hypotension with systolic blood pressure < 100 or diastolic blood pressure < 60mmHg
- ALT or AST above 3 x ULN or bilirubin >= 1.5 ULN at screening, known ascites
- Estimated glomerular filtration rate (eGFR CKD-EPI) below 30 ml/min/1.73 m2 at screening
- Any prior systemic anti-VEGF treatment or IVT anti-VEGF treatment in the study eye
- Any prior intraocular steroid injection in the study eye
- Any prior grid or focal laser photocoagulation within 500 microns of the foveal center or any prior PRP in the study eye
- Use of nitrates or NO donors (such as amyl nitrate) in any form including

topical; PDE5 inhibitors, non-specific PDE inhibitors within 1 week before first study drug administration

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2022
Enrollment:	9
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Runcaciguat
Generic name:	BAY 1101042

Ethics review

Approved WMO

Date:	05-02-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO Date:	01-04-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-05-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	28-05-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	27-11-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-01-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-05-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	19-05-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-10-2022
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	13-10-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-10-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-12-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-02-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-03-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-002333-15-NL
CCMO	NL75162.056.21