Erythropoetine effects on cycling performance.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21046

Source
NTR

Brief title
N/A

Health condition

Cycling (wielrennen), endurance performance (uithoudingsvermogen)

Sponsors and support

Primary sponsor: Internal (Centre for Human Drug Research)
Source(s) of monetary or material Support: Internal (Centre for Human Drug Research)

Intervention

Outcome measures

Primary outcome

Exercise tests

All subjects will breathe during the exercise test through a facemask that will be connected to an oxymeter to collect inspired and
expired gasses for analyzing:

- Oxygen consumption, VO2 (L/min)

- Carbon dioxide production, VCO2 (L/min)

- Respiratory minute ventilation, VE (L/min)

- Tidal volume, Vt (L)

- Respiratory frequency, Rf

- Maximal oxygen consumption, VO2,max (ml kg-1 min-1)

During the exercise tests blood will be collected at predetermined stages to measure:

- Lactate levels

- Tissue plasminogen activator

- Creatinine phosphokinase

- C-reactive protein levels

VO2 and VCO2 will be used to calculate:

- Ventilatory equivalent for oxygen (VE/VO2), eqVO2

- Ventilatory equivalent for carbon dioxide (VE/VCO2), eqVCO2
these values will be used to determine:

- Ventilatory threshold 1, VT1

- Ventilatory threshold 2, VT2

Physiological parameters that will be determined at VT1 and VT2:

- Oxygen consumption, VO2 (L/min)

- Oxygen consumption per kg, VO2 (L/min/kg)

- Percentage of maximal oxygen consumption, %VO2max (L/min)

- Power output, P (J/s)

- Power output per kg, P (J/s/kg)

Physiological parameters that will be determined at maximal effort:

- Maximal oxygen consumption, VO2max (L/min)

- Maximal oxygen consumption per kg, VO2max (L/min/kg)

- Maximal power output, Pmax (J/s)

- Maximal power output per kg, Pmax (J/s/kg)

- Lactate values

Other determinations:

- Lactate threshold 1, LT1

- Lactate threshold 2, LT2

- Cycling economy, CE (W L-1 min-1)

- Gross efficiency, GE (%)

- Heart rate (bpm)

- Systolic blood pressure (mmHg)

- Diastolic blood pressure (mmHg)

Competition

Maximal and submaximal exercise parameters that will be measured and calculated during the competition:

- Power (W)

- Heart rate (bpm)

- Systolic blood pressure (mmHg)

- Diastolic blood pressure (mmHg)

Secondary outcome

Safety markers:

Monitoring vital signs

o Pulse Rate (bpm)

o Systolic blood pressure (mmHg)

o Diastolic blood pressure (mmHg)

o Temperature measurements (ºC)

Electrocardiogram (ECG)

o Heart Rate (HR) (bpm), PR, QRS, QT, QTcB, QTcF

Clinical Laboratory Assessments

o Haematology

Ht must be <52o/o.

o Chemistry

o Urinalysis

o Coagulation (F1+2, D-Dimer, bTG, PF4, P-selectin, E-selectin, thrombomodulin, TXB2)

Doping detection:

Detection (positive/negative test) of EPO in urine samples from subjects

Study description

Background summary

Subjects will be recruited in The Netherlands.

Study objective

Treatment with rhEPO has no effects on performance parameters measures by exercise tests.

Study design

Efficacy and Biological Passport: Every two weeks

Safety: Continuously and every week at dosing, every 2 weeks at exercise tests.

Doping: at several timepoints

Intervention

Weekly subcutaneous doses of Neorecormon (5000 IU, or adjusted to reach the desired Hemoglobin increase, maximum dose is 10.000 IU). Additionally, all subject will receive Vitamin C supplementation.

Contacts

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Eligibility criteria

Inclusion criteria

1. Well-trained (as determined by cycling history and maximal power output >4 W/kg) male subjects, 18 to 45 years old (inclusive)

2. Subjects must be healthy / medically stable on the basis of clinical laboratory tests, medical history, vital signs, and 12-lead ECG performed at screening, including exercise ECG.

3. Each subject must sign an informed consent form

Exclusion criteria

1. Any clinically significant abnormality, as determined by medical history taking and physical examinations, obtained during the screening visit that in the opinion of the investigator would interfere with the study objectives or compromise subject safety.

2. Unacceptable known concomitant diagnoses or diseases at baseline, e.g., known cardiovascular, pulmonary, muscle, metabolic or haematological disease, renal or liver dysfunction, ECG or laboratory abnormalities, etc.

3. Unacceptable concomitant medications at baseline, e.g., drugs known or likely to interact with the study drugs or study assessments.

4. Unacceptable potential cycling performance enhancing medications at baseline, e.g. Erythropoiesis-stimulating agents, Anabolic Androgenic Steroids, Growth Hormone, Insulin, IGF-I and Beta-Adrenergic Agents or methods, e.g. altitude tents.

5. Blood transfusion in the past three months.

6. Loss or donation of blood over 500 mL within three months.

7. Participation in a clinical trial within 90 days of screening or more than 4 times in the previous year.

8. Known hypersensitivity to the treatment or drugs of the same class, or any of their excipients.

9. Any known factor, condition, or disease that might interfere with treatment compliance, study conduct or
interpretation of the results such as drug or alcohol dependence or psychiatric disease.

10. Positive urine drug test at screening, during visits at the clinical research unit and during the competition.

11. Positive alcohol breath test at screening, during visits at the clinical research unit and during the competition.

12. Haemoglobin (Hb) concentration > 9.8 mmol/l at screening.

13. Hb concentration < 8 mmol/l at screening.

14. Haematocrit (Ht) ≥ 48% at screening.

15. Ferritin < 80 ng/mL

16. Being subject to WADA’s anti-doping rules, meaning being a member of an official cycling

union or other sports union for competition (such as the KNWU) or participating in official competition during the study.

17. Positive results from serology at screening (except for vaccinated subjects or subjects with past but resolved hepatitis)

18. Previous history of fainting, collapse, syncope, orthostatic hypotension, or vasovagal reactions.

19. Any circumstances or conditions, which, in the opinion of the investigator, may affect full participation in the study or compliance with the protocol.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-01-2016
Enrollment:	48
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-01-2016
Application type:	First submission

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
NTR-new	NL5516
NTR-old	NTR5643
Other	: CHDR1514

Study results