Differences in effect of treatment with mepolizumab and benralizumab on resident and inflammatory eosinophils

Published: 03-02-2020
Last updated: 15-05-2024

The study objective of the trial was to test the hypothesis that treatment with mepolizumab only affects inflammatory eosinophils whereas treatment with benralizumab affects both inflammatory and resident eosinophils.

Ethical review	Approved WMO
Status	Other
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON26743

Source
Nationaal Trial Register

Brief title
DIMENSION

Condition

- Bronchial disorders (excl neoplasms)

Synonym
Severe eosinophilic asthma

Research involving
Human

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Number of eosinophils per high power field in rectal tissue

Secondary outcome

Kinetics of tissue eosinophils determined by metabolic labeling with deuterated glucose

Study description

Background summary
Nowadays patients with severe eosinophilic asthma can be treated with monoclonals directed against the cytokine IL5 (mepolizumab/reslizumab) or its receptor (benralizumab). The literature suggests that anti-IL-5 antibodies only affect inflammatory eosinophils whereas benralizumab also depletes resident cells. The role of resident eosinophils is unknown and therefore it is important to compare both therapies.

Study objective
The study objective of the trial was to test the hypothesis that treatment with mepolizumab only affects inflammatory eosinophils whereas treatment with benralizumab affects both inflammatory and resident eosinophils.

Study design
Open label prospective comparison between treatment with benralizumab and mepolizumab. Data were compared with data obtained from healthy volunteers..

Intervention

One arm mepolizumab and the other arm benralizumab

Study burden and risks
Minimal.

Contacts

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Eligibility criteria

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

Inclusion criteria

• Age ≥ 18 • Diagnosis of severe refractory eosinophilic asthma • Eligible for mepolizumab or benralizumab therapy according the national recommendations for severe asthma of the Dutch society for lung diseases and tuberculosis (NVALT guideline 2013): Patients with asthma, for whom alternative diagnoses are excluded, comorbidity optimally treated, provoking factors minimized and therapy compliance optimized, but despite this still have insufficient asthma control (≥ 1.5 ACQ-7 or other questionnaire) or frequent (≥2 annually) severe exacerbations (systemic CS needed) while routinely using high-dose asthma medication (≥ 1000 mcg/day fluticasone propionate equivalent and/or daily OCS in combination with LABA or other controller medication); or patients who can achieve asthma control only with systemic CS and are therefore are risk for adverse effects or the corticosteroids. • Treated with mepolizumab or benralizumab for at least 4 months. • Before treatment with biologics a blood eosinophilia (≥ 150 eosinophils/□l blood) irrespective of steroid use

Exclusion criteria

• Any infection (eg. HIV, Hepatitis, STDs) • Insulin dependent diabetes • Smoking at present or in the last 12 months and/or a past history of more than 10 pack years • Proven allergic bronchopulmonary aspergillosis • Auto-immune diseases • Use of medication, excluding: o Anticonceptives o Pain killers, if used less than once a week • exuberant alcohol consumption (for males > 36 glasses per week, for females >24 glasses per week) • Drug use • History of cancer • Use of biologicals other than mepolizumab or benralizumab • daily oral steroid therapy during the three months preceding inclusion

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	17-02-2023
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	10-09-2020
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

ID: 52251
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8361
CCMO	NL74748.041.20
EudraCT	2019-004676-18
OMON	NL-OMON52251

Study results

Date completed: 01-10-2023

Summary results
prematurely terminated