# Eclipse extension.

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To define the parameters and to identify new biomarkers which predict disease progression in individuals with different COPD phenotypes. To follow a subgroup of the ECLIPSE cohort the predictive values of the variables will be enhanced with an...

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|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestopt |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON29112

**Bron**
Nationaal Trial Register

**Verkorte titel**
Eclipse extension

**Aandoening**

COPD, biological markers

### Ondersteuning

**Primaire sponsor:** Centrum: CIRO+, expertisecentrum voor chronisch orgaanfalen.
Plaats: Horn
Hoofdonderzoeker:Prof. Dr. E.F.M. Wouters
**Overige ondersteuning:** Centrum: CIRO+, expertisecentrum voor chronisch orgaanfalen.
Plaats: Horn
Hoofdonderzoeker:Prof. Dr. E.F.M. Wouters

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The primary study parameters of ECLIPSE extension with an additional three years follow-up are:<br>
1. The 6 years natural history of the following phenotypes of COPD: GOLD stage II till IV; cachexia; respiratory failure; frequent exacerbators; and predominantly emphysema and predominantly airway disease;<br>
2. The relationship between the progressions of the above phenotypes;<br>
3. How the baseline data of ECLIPSE predicts the above phenotypes;<br>
4. How the progression of the above phenotypes relates to all-cause mortality and mortality of COPD.

# Toelichting onderzoek

**Achtergrond van het onderzoek**

Title:

ECLIPSE extension, an additional 3 year extra follow up to the original 3 year longitudinal prospective study to identify novel endpoints and compare these with forced expiratory volume in 1 second (FEV1) for their ability to measure and predict Chronic obstructive pulmonary disease (COPD) severity and its progression over time (ECLIPSE).

Rationale:

This study aims to examine the natural history of disease history of specific COPD phenotypes and their baseline predictors to enhance an improved understanding of the mechanisms causing COPD. With these (new) predictors the characterisation of the natural history of COPD disease progression and phenotypes for clinical research will be enhanced. Clinical studies shall have more success to describe drug mechanisms and contribute to better disease understanding.

The ECLIPSE study to describe disease progression with a 3 years follow-up is a short period of time. A longer than 3 year of follow-up will work to improve the characterisation of the disease progression and likely enhance the prognostic value of baseline data.

Objective:

To define the parameters and to identify new biomarkers which predict disease progression in individuals with different COPD phenotypes. To follow a subgroup of the ECLIPSE cohort the

predictive values of the variables will be enhanced with an additional 3 year follow up and to improve the characterisation of the natural history of some specific COPD phenotypes.

Study design:

An extension of the ECLIPSE study (SCO104960) with an additional 3 years with annual visits and phone contacts every 3 months.

Study population:

Only participants of the ECLIPSE study (SCO104960) who gave consent for an additional 3 year follow-up.

Primary study parameters/endpoints:

The primary study parameters of ECLIPSE extension with an additional three years follow-up are:

1. The 6 years natural history of the following phenotypes of COPD: GOLD stage II till IV; cachexia; respiratory failure; frequent exacerbators; and predominantly emphysema and predominantly airway disease;

2. The relationship between the progressions of the above phenotypes;

3. How the baseline data of ECLIPSE predicts the above phenotypes;

4. How the progression of the above phenotypes relates to all-cause mortality and mortality of COPD.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

There are no major risks associated with participation. The tests will be annually repeated. Some persons experience the lung function tests exhausting and repeating. Sometimes a temporary feeling of tachycardia and palpitations can be experienced after inhalation of albuterol or salbutamol. The assessment of lung function is an accepted diagnostic procedure also usual executed in hospitals and medical clinics. Rarely feelings of dyspnoea are experienced. Blood drawn: Usually drawing blood with a needle are not causing major side effects. A blood draw can cause some bleeding, blue spot, inconvenience, infection and/or

pain at the place where the blood was drawn. The risk of infections is low. During the measurement of blood pressure the blood flow is temporarily interrupted. This can cause some excitation. Immediate after the measurement of blood pressure the blood flow is normal. With the carbon monoxide measurement the participants have to breathe as usual and exhale in the equipment for at least 10 seconds. For the body composition the participants are lying on an examination couch. The particiants have to undress the upper part of the body for the ECG. COPD patients can experience fatigue and dyspnoea with taking clothes off.

**Doel van het onderzoek**

To define the parameters and to identify new biomarkers which predict disease progression in individuals with different COPD phenotypes. To follow a subgroup of the ECLIPSE cohort the predictive values of the variables will be enhanced with an additional 3 year follow up and to improve the characterisation of the natural history of some specific COPD phenotypes.

**Onderzoeksopzet**

An extension of the ECLIPSE study (SCO104960) with an additional 3 years with annual visits and phone contacts every 3 months.

**Onderzoeksproduct en/of interventie**

N/A

# Contactpersonen

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A COPD subject will be eligible for inclusion in this study only if all of the following criteria apply:

1. Male or female subjects, aged 40-75 years inclusive;

2. A baseline (post-bronchodilator) FEV1 <80% of predicted normal and a baseline (post-bronchodilator) FEV1/FVC ratio ≤70%;

3. Current or ex-smokers with a smoking history of at least 10 pack-years (number of pack years = (number of cigarettes per day / 20) x number of years smoked e.g. 20 cigarettes per day for 10 years, or 10 cigarettes for 20 years);

4. A signed and dated written informed consent is obtained prior to participation;

5. Able to comply with the requirements of the protocol and be available for study visits over 3 years.

For the ECLIPSE extension:

6. ECLIPSE participants willing and able to continue in a 3-year extension;

7. A signed and dated written informed consent for the extra 3 year of follow up is obtained prior to participation.

A control subject will be eligible for inclusion in this study only if all of the following criteria apply:

1. Male or female subjects, aged 40-75 years inclusive, who are free from significant disease as determined by history, physical examination and screening investigations;

2. A baseline (post-bronchodilator) FEV1 > 85% of predicted normal and a baseline (postbronchodilator) FEV1/FVC ratio > 70%;

3. Current or ex-smokers with a smoking history of at least 10 pack-years (number of pack years = (number of cigarettes per day / 20) x number of years smoked e.g. 20 cigarettes per day for 10 years, or 10 cigarettes for 20 years);

4. A signed and dated written informed consent is obtained prior to participation;

5. Able to comply with the requirements of the protocol and be available for study visits over 3 years.

For the ECLIPSE extension:

6. ECLIPSE participants willing and able to continue in a 3-year extension;

7. A signed and dated written informed consent for the extra 3 year of follow up is obtained prior to participation.

A non-smoking control subject will be eligible for inclusion in this study only if all of the following criteria apply:

1. Male or female subjects, aged 40-75 years inclusive, who are free from significant disease as determined by history, physical examination and screening investigations;

2. A baseline (post-bronchodilator) FEV1 > 85% of predicted normal and a baseline (post-bronchodilator) FEV1/FVC ratio > 70%;

3. Non-smokers with a smoking history < 1 pack-year (number of pack years = (number of cigarettes per day / 20) x number of years smoked);

4. A signed and dated written informed consent is obtained prior to participation;

5. Able to comply with the requirements of the protocol and be available for study visits over 3 years.

For the ECLIPSE extension:

6. ECLIPSE participants willing and able to continue in a 3-year extension;

7. A signed and dated written informed consent for the extra 3 year of follow up is obtained prior to participation.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A COPD subject will not be eligible for inclusion in this study only if all of the following criteria apply:

1. Known respiratory disorders, or disorders identified at screening/visit 1 (including identification on the first CT-scan), other than COPD (e.g.: lung cancer, sarcoidosis, tuberculosis, lung fibrosis, cystic fibrosis);

2. Known history of significant inflammatory disease, other than COPD (e.g. rheumatoid arthritis and Lupus);

3. Known to be severely alpha-1-antitrypsine deficient (PI SZ or ZZ);

4. Having undergone lung surgery (e.g. lung reduction, lung transplant);

5. Have cancer or have had cancer in the 5 years prior to study entry;

6. Serious, uncontrolled disease (including serious psychological disorders) likely to interfere with the study or impact on subject safety;

7. Is enrolled in a long term blinded drug study (subjects in open label studies may be considered and subjects in short blinded studies (approx less than 12 weeks may be considered following consultation with sponsor) or a study where there is significant radiation exposure (e.g.: CT scans);

8. Have, in the opinion of the investigator, evidence of alcohol, drug or solvent abuse;

9. Have received a blood transfusion in the 4 weeks prior to study start;

10. Has experienced a moderate or severe exacerbation (requiring oral corticosteroid, antibiotics or hospitalisation) within the last 4 weeks. All courses of oral corticosteroids and antibiotics must be completed at least 2 weeks before study start;

11. Is on long term oral corticosteroids (long term is considered use for more than 3 consecutive months);

12. Unable to walk;

13. Subject is participating investigator, sub-investigator, study co-ordinator, or employee of a participating investigator, or is an immediate family member of the aforementioned.

For the ECLIPSE extension:

14. Known significant inflammatory disease, other than COPD (e.g. rheumatoid arthritis and Lupus);

15. Having undergone lung surgery (e.g. lung reduction, lung transplant);

16. Serious, uncontrolled disease (including serious psychological disorders) likely to interfere with the study or impact on subject safety;

17. Have, in the opinion of the investigator, evidence of alcohol, drug or solvent abuse.

A control subject will not be eligible for inclusion in this study only if all of the following criteria apply:

14. Known respiratory disorders, or disorders identified at screening/visit 1 including identification on the first CT-scan (e.g.: COPD, asthma, lung cancer, sarcoidosis, tuberculosis, lung fibrosis);

15. Known history of significant inflammatory disease, other than COPD (e.g. rheumatoid arthritis and Lupus);

16. Known to be severely alpha-1-antitrypsine deficient (PI SZ or ZZ);

17. Having undergone lung surgery (e.g. lung reduction, lung transplant);

18. Have cancer or have had cancer in the 5 years prior to study entry;

19. Serious, uncontrolled disease (including serious psychological disorders) likely to interfere with the study;

20. Is enrolled in a long term blinded drug study (subjects in open label studies may be considered and subjects in short blinded studies (approx less than 12 weeks may be considered following consultation with sponsor) or a study where there is significant radiation exposure (e.g.: CT scans);

21. Have, in the opinion of the investigator, evidence of alcohol, drug or solvent abuse;

22. Have received a blood transfusion in the 4 weeks prior to study start;

23. Is on long term oral corticosteroids (long term is considered use for more than 3 consecutive months);

24. Subject is participating investigator, sub-investigator, study co-ordinator, or employee of a participating investigator, or is an immediate family member of the aforementioned.

For the ECLIPSE extension:

25. Known significant inflammatory disease, other than COPD (e.g. rheumatoid arthritis and Lupus);

26. Having undergone lung surgery (e.g. lung reduction, lung transplant);

27. Serious, uncontrolled disease (including serious psychological disorders) likely to interfere with the study or impact on subject safety;

28. Have, in the opinion of the investigator, evidence of alcohol, drug or solvent abuse.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Niet-gerandomiseerd |

**Controle:** N.v.t. / onbekend

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestopt |
| (Verwachte) startdatum: | 15-12-2010 |
| Aantal proefpersonen: | 120 |
| Type: | Werkelijke startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 02-01-2012 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL3073 |
| NTR-old | NTR3221 |
| Ander register | METC Zuidwest-Holland : 10-149/P06.0460L |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A