**Study Specific SOP**

|  |  |
| --- | --- |
| **Title:** | Cardiopulmonary exercise testing (CPET) SOP EPOCH CPET |
| **Doc Name:** | SOP\_CPET\_01 |
| **Version:** | 1 |
| **Effective date:** | 25.09.2019 |
|  | Name, Function | Date |
| **Author** | Markus Schwerzmann | 28.04.2019 |
| **Release by PI** | Matthias Greutmann | 25.09.2019 |

Table of Content

 Page

[1 Purpose 3](#_Toc486852901)

[2 Scope 3](#_Toc486852902)

[3 Abbreviations 3](#_Toc486852903)

[4 Procedure 3](#_Toc486852904)

[4.1 General 4](#_Toc486852905)

[4.2 Study preparation 4](#_Toc486852906)

[4.3 Performing study 5](#_Toc486852907)

[4.4 Results / Report 5](#_Toc486852908)

# Purpose

The purpose of this SOP is to describe the standards for performing a cardiopulmonary exercise test as part of the EPOCH studies.

# Scope

The SOP is valid for all clinical research functions participating at EPOCH ASO STUDY and aims to improve the comparability of CPET exams performed at different investigating sites. The SOP shall set a common standard for the performing a cardiopulmonary exercise test in compliance with GCP, other SOP and regulatory requirement(s).

# Abbreviations

|  |  |
| --- | --- |
| CPET | cardiopulmonary exercise testing |
| ECG | electrocardiogram |
| FVC | forced vital capacity |
| FEV | forced expiratory volume |
| FEV1 | forced expiratory volume in the first second |
| VO2 | oxygen consumption |
| VCO2 | carbon dioxide production |
| PETO2 | partial pressure of end-tidal oxygen |
| PETCO2 | partial pressure of end-tidal carbon dioxide |
| VE | ventilation |
| HR | heart rate |
| HRR | heart rate recovery |
| RQ | respiratory quotient (VCO2/VO2) |

# Procedure

## General

|  |  |
| --- | --- |
| **Responsibility** | **Procedure** |
| Study nurse and/or cardiologist | Plan CPET study, inform patient to bring sports gear and to only eat a light meal before the CPET |
|  | Prepare a room with ECG, spiroergometry system and electronically braked cycle ergometer  |

## Study preparation

|  |  |
| --- | --- |
| **Responsibility** | **Procedure** |
| Assistant doctor and/or sports scientist | Measure patient height and weight |
|  | Connect Twelve-lead ECG with patient laying down* Measure resting ECG and HR
* Measure resting blood pressure (≥ 5 min of laying down) with an automatic device twice on the right arm and once on the left arm. The lowest value is taken.
* Register ECG date, HR and rhythm on CRF sheet
 |
|  | Perform spirometry 3 times * Register best performance FVC and FEV1 on CRF sheet
 |
|  | CPET on cycle with ergometry, ECG registration and blood pressure measurement* Connect gas analyser and perform local calibration protocol before every CPET
* Make sure patient cannot to see the amount of Watt during cycling. RPM should be visible.
 |

## Performing study

|  |  |
| --- | --- |
| **Responsibility** | **Procedure** |
| Study nurse and/or cardiologist | Test protocol for VO2peak :* Start recording
* 3 min resting phase sitting quietly on ergometer without talking
* Measure baseline blood pressure in second minute and HR in third minute while sitting on the bicycle
* Cycle for 3 min at 0 Watt for RAMP 5 protocol or at 20 Watt for other protocols with a RPM between 60-80
* Choose individualized RAMP protocol resulting in optimal test duration 8–12 min
	+ RAMP 10 (10 Watt/min)
	+ RAMP 15 (15 Watt/min)
	+ RAMP 20 (20 Watt/min)
* Use the same protocol for follow-up test

Start RAMP and let patient cycle between 60-80 RPM**Protocol for treadmill:**" The initial speed of 3 km/h is maintained for the first 2 minutes and, thereafter, an increase of 0.3 km/h for every subsequent minute is added. The initial slope is zero, increasing 1.4 % after the second stage until a maximum of 12%." |
|  | Terminate the test when patient is exhausted despite verbal encouragement: * Aim at RQ > 1.1
* Aim at Borg scale (6-20) > 17
 |
|  | After termination of the test, let the patient continue cycling for at least 1 min at 5 watt and at 60 RPM* Register reason for test termination and BORG score on CRF sheet
* Register HR after 1 min

Stop data recording only shortly before patient dismounts from the ergometer |

## Results / Report

|  |  |
| --- | --- |
| **Responsibility** | **Procedure** |
| PI of each centre | Analyse data locally (nor core lab) |
|  | The following data should be collected and reported:- bicycle/treadmill- peak Watt- peak Watt % predicted- peak VO2, defined as the highest value of oxygen consumption during the last 30 s of peak exercise- peak VO2 % predicted- VE/VCO2 slope\*- O2 pulse trajectory\*- VO2/delta Watt trajectory\*- Arrhythmias at 12-lead ECG - ST-segment depression (J-point during exercise)Reporting of these data will follow the recommendations of the European Association for Cardiovascular Prevention and Rehabilitation (EACPR / AHA joint scientific statement. Clinical recommendations for cardiopulmonary exercise testing data assessment in specific patient populations, Eur. Heart J. 2012:33;2917–2927) |