Kinetics of left ventricular strains and untwist during the transitions from rest to exercise

Submission date 05/12/2017	Recruitment status No longer recruiting	Prospectively registered	
		 Protocol Statistical analysis plan 	
Registration date 23/03/2018	Overall study status Completed	[X] Results	
Last Edited 13/01/2022	Condition category Circulatory System	[_] Individual participant data	

Plain English summary of protocol

Background and study aims

During the transitions from rest to exercise, oxygen uptake is limited by muscle oxygen delivery, which directly depends of the response of the cardiorespiratory system (heart and lungs) at the start of the exercise. Endurance training is known for allowing a faster cardiac (heart) adaptation. However, data about cardiac adaptation during the transition from rest to exercise are limited to heart rate, stroke volume and cardiac output. Today, new advances in echocardiography based on speckle tracking can be used to measure regional left ventricular (LV) strains and twist. The aim of this study is to assess regional LV strains and twist of endurance trained cyclists compared to sedentary adults at the onset of dynamic exercise.

Who can participate? Young male cyclists and healthy volunteers aged 18-35

What does the study involve?

The participants perform five similar constant work-load exercises on an exercise bicycle (target heart rate: 130 bpm), in order to measure myocardial (heart muscle) strains with speckle-tracking echocardiography (a type of ultrasound scan). Heart function is assessed every 15 seconds during the first minute and then every 30 seconds up until 240 seconds.

What are the possible benefits and risks of participating? Participants may benefit from a clinical examination performed by a cardiologist. Exercises are performed at submaximal intensities (corresponding to 130 bpm). Therefore, there are no risks for participants.

Where is the study run from? University of Avignon (France)

When is the study starting and how long is it expected to run for? January 2015 to December 2017

Who is funding the study? University of Avignon (France) Who is the main contact? 1. Dr Stephane Nottin stephane.nottin@univ-avignon.fr 2. Dr Omar Izem omizem@gmail.com

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers KINETICS01

Study information

Scientific Title

Kinetics of left ventricular function and regional mechanics at the onset of exercise in sedentary and endurance-trained subjects

Study objectives

The trialists hypothesized that the fast increase of stroke volume at the onset of exercise would result mainly from a rapid improvement in diastolic function implying an important contribution of LV untwist. They hypothesized that these mechanisms adapted better in endurance-trained subjects.

Ethics approval required Old ethics approval format

Ethics approval(s)

University of Avignon ethics committee

Study design Observational study

Primary study design Observational

Secondary study design Cross sectional study

Study setting(s) Other

Study type(s)

Other

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Cardiac evaluations at rest and during effort in healthy young controls and endurance-trained cyclists

Interventions

This study was a pilot study to check the feasibility of fast evaluation of echocardiography every 15 seconds during exercise. Young male cyclists (18 – 25 years) and age-matched sedentary controls performed five similar constant work-load exercises on a cyclo-ergometer (target heart rate: 130 bpm), in order to follow kinetics of diastolic and systolic myocardial strains by speckle-tracking echocardiography with high temporal resolution. Cardiac function was assessed every 15 seconds during the first minute and then every 30 seconds up until 240 seconds.

Intervention Type

Other

Primary outcome measure

Left ventricular strains and twist/untwist kinetics during the transitions from rest to exercise, measured non-invasively using 2D-strain echocardiography. Each subject of the study was evaluated one time only (i.e. transversal design)

Secondary outcome measures

Global systolic and diastolic functions, measured non-invasively using Doppler echocardiography. Each subject of the study was evaluated one time only (i.e. transversal design)

Overall study start date 01/01/2015

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Completion date 20/12/2017

Eligibility

Key inclusion criteria

1. Cyclists training at least 10 hours per week for at least 8 years or sedentary young men reporting regular training habits

- 2. 18-35 years old
- 3. Non-smokers
- 4. No history of diabetes, hypertension or cardiovascular disease
- 5. Normal clinical examination
- 6. In sinus rhythm

7. Screening echocardiography showing normal left and right heart morphology and function and the absence of valvular disease

Participant type(s)

Healthy volunteer

Age group

Adult

Lower age limit

18 Years

Upper age limit

35 Years

Sex

Male

Target number of participants

25 subjects in each group

Key exclusion criteria

1. Smokers

- 2. History of diabetes, hypertension or cardiovascular disease
- 3. Abnormal sinus rhythm

4. Screening echocardiography shows abnormal left and right heart morphology and function and or valvular disease

Date of first enrolment

01/09/2015

Date of final enrolment 20/12/2016

Locations

Countries of recruitment France **Study participating centre University of Avignon** France 84000

Sponsor information

Organisation University of Avignon

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Sponsor type University/education

Website http://www.univ-avignon.fr

ROR https://ror.org/00mfpxb84

Funder(s)

Funder type University/education

Funder Name University of Avignon

Results and Publications

Publication and dissemination plan

The trialists plan two publications in high-impact peer reviewed journals. The first one will be sent soon to the Journal of Physiology (London) and the second will be sent to Medicine & Science in Sports & Exercise.

Intention to publish date

01/02/2018

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>		01/11/2021	13/01/2022	Yes	No