

Official Title of the study:

**Assessment of the Acute Effect of
Cycling Practice in Lumbar and Thigh
Muscles**

NCT number: *NCT03442933*

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I. Study Protocol

The main objective of this study is to evaluate the behavior of the mechanical characteristics of the lower back and thigh muscles, by means of tensiomyography, in amateur cyclists after an acute effort on road and mountain bikes, and to study their possible relationship with low back pain. Material and methods: Cross-sectional randomized clinical trial. A single group ($n = 40$) of amateur cyclists was set up and subjected to 2 different intervention conditions: a road bike time trial (CA) and a mountain bike time trial (MT). The behavior of the mechanical characteristics of the musculature of the lower back and thigh, in amateur cyclists, before and after an acute effort (> 3 hours) in CA and MT bicycle, was evaluated using the tensiomyographic variables of delay time (Td), contraction time (Tc), maximal radial displacement (Dm), relaxation time (Tr) and sustain time (Ts). The thigh muscles selected from the thigh were: vastus medialis (VM), rectus femoris (RF), vastus lateralis (VL), biceps femoris (BF), and erector spinae (EE) at the lumbar level. Pain assessment was carried out using the perceived pain scale (EVA), the pressure pain threshold (UDP) and the Roland-Morris questionnaire (RMQ).

II. Statistical Analysis Plan

The statistical analysis was performed with the SPSS v.21. To assess the effect of cycling practice on the mechanical characteristics of the muscles, a multivariate analysis (MANOVA) was performed. The level considered significant was established at 0.05 in all the analysis carried out.

III. Informed Consent Form

FACT SHEET PARTICIPANTS

ESTUDY TITTLE: "Assessment of the Acute Effect of Cycling Practice in Lumbar and Thigh Muscles".

PROMOTER OF THE STUDY:

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Through this document the recipient is invited to participate in a research study promoted by the European University of Madrid on the acute response of the muscles of the back and thigh in road and mountain bikers. Before deciding whether to participate in this study, it is important that you understand why this research is necessary, which will involve your participation, how your information will be used and its possible benefits, risks and discomforts. Please take the time to read carefully the information provided below.

STUDY SUMMARY:

The two most important problems of the musculoskeletal system in cyclists are low back pain (60%) and knee pain (33%). There is no clear hypothesis about the development of low back pain in cyclists, but several authors agree that it may be due to maintaining a maintained posture, with the lumbar spine in inversion and the characteristics associated with this sport (long duration, static posture, high intensities). The project proposes to analyze the acute effect of a long-term bicycle trip (≥ 3 hours) on the muscles involved in low back and knee pain, see, lumbar paravertebral, quadriceps and hamstrings, by means of tensiomyography (TMG) .

VOLUNTARY PARTICIPATION AND WITHDRAWAL OF THE STUDY:

The participation in the study is totally voluntary, being possible to withdraw from it at any time, without altering the investigator-participant relationship, nor any damage as a result of that relationship.

In case you decide to leave the study, the participant may do so by allowing the use of the data obtained so far for the purpose of the study or, if it were his will, these data would be erased from the computer files.

Who can participate?

It is required to meet the following inclusion criteria: be a man, with an age between 18 and 55 years, with an experience in the practice of cycling over 3 years, having accumulated at least 200 hours of training annually. Not having received specific treatment for the lumbar area in the last 4 weeks, or, being subjected to any treatment currently in evaluated musculature, and not suffering from pathology diagnosed in the anatomical regions interested in the study. And, finally, sign the informed consent.

Excluded criteria will have been to have performed strenuous exercise in the previous 48 hours, as well as having taken energy drinks, alcohol or caffeine in the 3 hours prior to the data collection; Do not complete the bike ride due to loss in the course or suffer any mechanical failure that prevents the continuity of the same.

What is the participation of each subject?

The participation in the study requires only 2 assistances to the data takings, separated by a week among themselves, that will be developed in the training laboratory of the Faculty of Sciences of Physical Activity and Sport of the European University. Each participant will be evaluated under two conditions: road cyclist and mountain cyclist. Said sessions will begin with an initial assessment, in which an anthropometric assessment (height and weight), an assessment of pain perceived with the EVA scale and the pain threshold with algometry will be made. A muscular evaluation with tensiomyography, a non-invasive tool that allows us to evaluate the contractile properties of superficial muscles through an isometric contraction induced by electrostimulation, and the assessment of mobility and flexibility of the lumbar spine.

Once the initial assessment is complete, participants will perform a brief 5-minute warm-up on a stationary bicycle by replicating the measurements of their bicycle. They will repeat, once again, the initial evaluations and will make an exit by bicycle through a previously programmed route and of an approximate duration of 3 hours. Upon their return, the participants will re-perform all previous assessments.

Requirements to the participants for the day of the evaluation

Participants are asked to attend the data collection fully rested, having made the trip to the facilities by car and never by bicycle. Otherwise, this could affect the initial measurements. Bring your own bicycle with you since the weight and height and back of the saddle and handlebars will be recorded. They come with shaved legs, and bring a sports shorts and shirt for measurements, because, if for example the measurements are made in quadriceps with the rolled up colutte, the pressure exerted by this on the

musculature would affect the results. It is recommended to bring a towel to dry the sweat at the end of the exit. All participants can change at the same facilities, as well as take a shower at the end.

BENEFITS AND RISKS DERIVED FROM PARTICIPATION IN THE STUDY

Your participation in the study can help you to control risk factors associated with sports injuries in the practice of cycling and, therefore, to optimize sports performance and maintain a healthy state. It is expected that the information obtained may benefit other cyclists in the future and may contribute to a better understanding of the muscle contraction process and that this may be related to the presence of back pain.

The assessments of the study will not pose any risk to your health. As for the electrical stimulation of the Tensiomyography, it is very low intensity. In any case, the stimulus intensity that can reach the electrostimulator does not exceed 110 milliamps, well below the minimum value for this type of current, direct current, may cause ventricular fibrillation. It can only be a little unpleasant at the time of muscle stimulation. As for the departure by bike, the risks inherent in the practice of cycling are well known: injuries, falls, collisions, etc. At the end of the investigation you can be informed, if you wish, about the main results and the general conclusions of the study.

The investigators in charge of performing the tensiomyographic assessments have experience in the use of the Tensiomyography. Likewise, one of the members of the research team is a member of the International Society of Tensiomyography (ISOT).

CONFIDENTIALITY

The treatment, communication and transfer of personal data of all participating subjects will comply with the provisions of Organic Law 15/1999, of December 13, on the Protection of Personal Data. In accordance with the aforementioned legislation, you can exercise the rights of access, modification, opposition and cancellation of data, for which you should contact the study sponsor.

The data collected for the study will be identified by a code and only the principal investigator of the study / collaborators will be able to relate said data with you. Therefore, your identity will not be disclosed to any person except for exceptions of legal requirement.

ECONOMIC COMPENSATION

No type of financial compensation is expected during the study.

OTHER RELEVANT INFORMATION

If you decide to withdraw your consent to participate in this study, no new data will be added to the database and you may demand the destruction of your data and / or all identifiable samples previously held to prevent further analysis.

You should also know that you can be excluded from the study if the investigators consider it appropriate, either for security reasons, for any adverse event that occurs or because you believe that you are not complying with the established procedures. In either case, you will receive an adequate explanation of the reason for your withdrawal from the study. By signing the consent form, you agree to comply with the study procedures that have been presented to you.

QUESTIONS

If you have any questions about any aspect of the study or would like to comment on some aspect of this information, please do not hesitate to ask the members of the research team. In case after reading this information and clarifying the doubts, decide to participate in the study, you must sign your informed consent.

INFORMED CONSENT OF PARTICIPATION IN THE STUDY

“Assessment Of The Acute Effect Of Cycling Practice In Lumbar And Thigh Muscles”

Participants name:

I have read the information sheet, I have understood the explanations given to me, as well as the possible complications and risks. Therefore, I declare to be correctly informed according to the provisions of article 4 of Law 41/2002, of November 14, and I give my consent to participate in the research study.

Place and Date: _____ in _____ of 20 _____

Signature: _____

National identity document: _____