- Biomarqueurs biologiques de stress
- WHO approved registry: why? how?
- Stratégie de publication: Trials

Fred Dutheil – CHU Clermont-Ferrand
Do Well B.?
Saint-Nectaire – le 25 juin 2013

CHU CLERMONT FERRAND

Biomarqueurs de stress

JOBSTRESS study: Comparison of heart rate variability in emergency physicians working a 24-hour shift or a 14-hour night shift — A randomized trial

Frédéric Dutheil [a,b,c,d,*], Gil Boudet [b], Christophe Perrier [a], Gérard Lac [c], Lemlih Ouchchane [e], Alain Chamoux [b], Martine Duclos [d], Jeannot Schmidt [a]

doi:10.1016/j.ijcard.2012.04.141

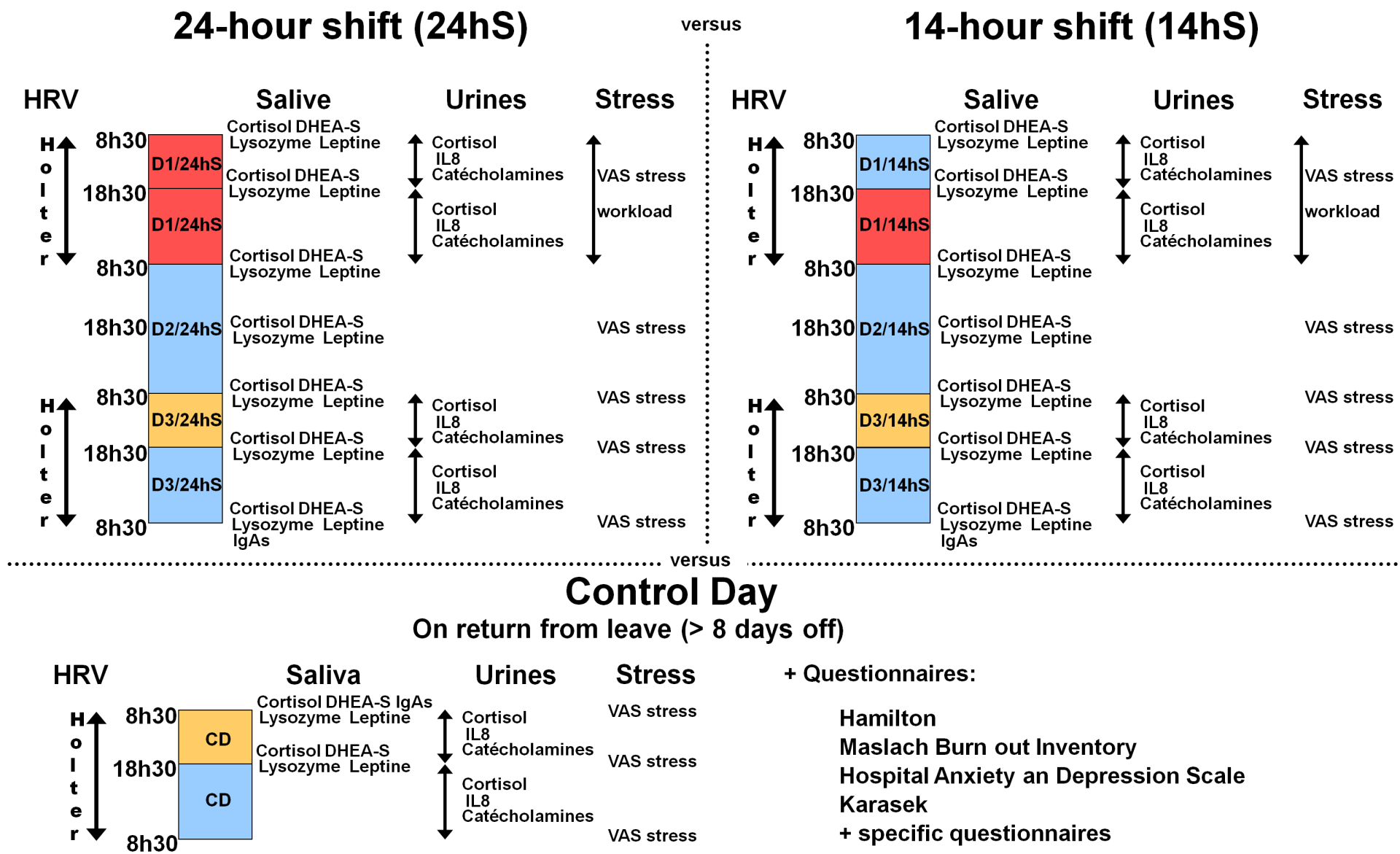
International Journal of CARDIOLOGY

Use of heart rate variability to detect stressing professional events among emergency physicians

F. Dutheil[a,*,b,c,d], G. Boudet[a], C. Perrier[b], G. Lac[c], L. Ouchchane[d], G. Brousse[b], M. Duclos[e], A. Chamoux[a], J. Schmidt[b]

Archives des Maladies Professionnelles et de l'Environnement 2012;73:334-338

ELSEVIER MASSON



versus

Control Day

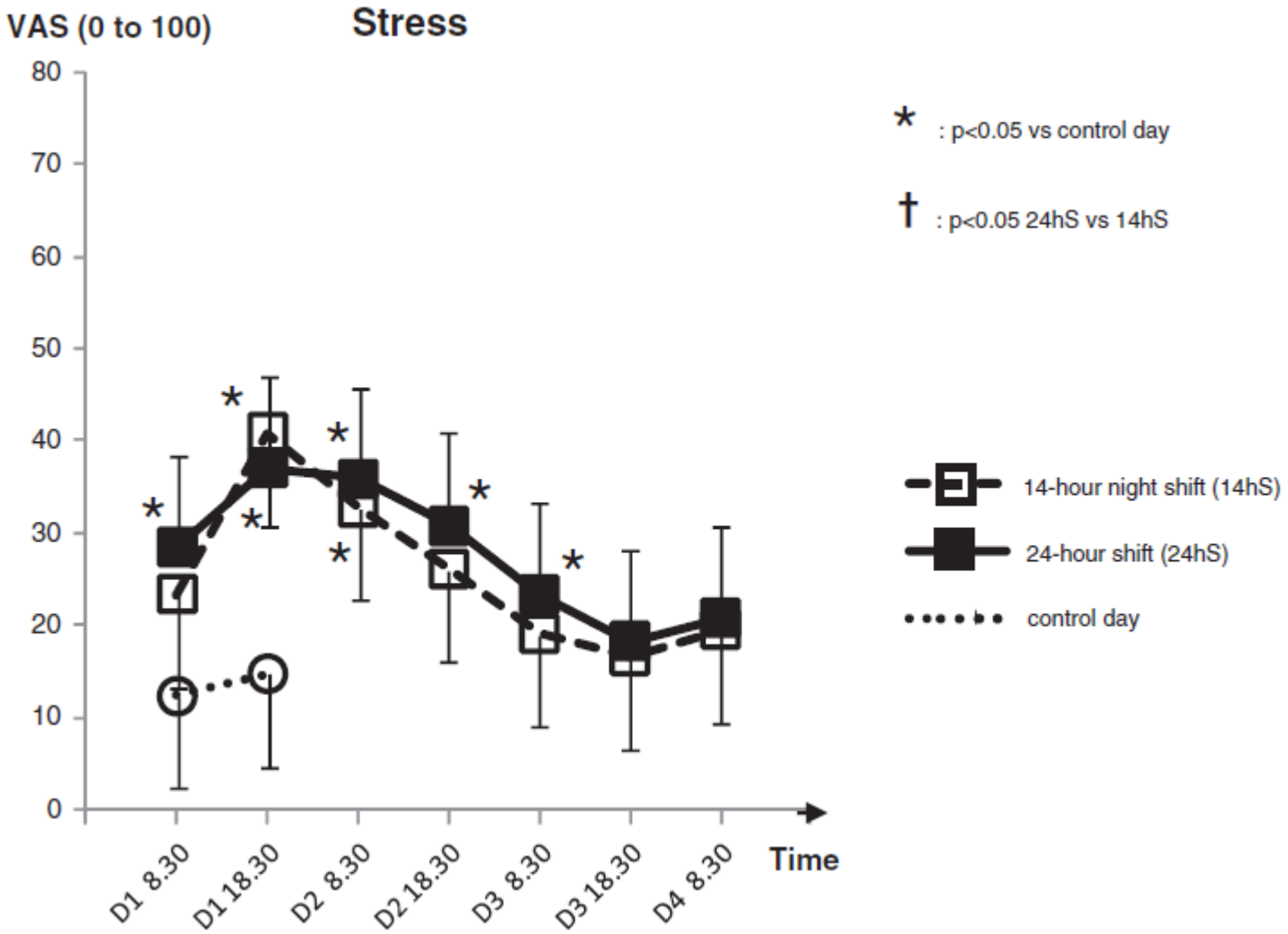
On return from leave (> 8 days off)

+ Questionnaires:

- Hamilton
- Maslach Burn out Inventory
- Hospital Anxiety an Depression Scale
- Karasek
- + specific questionnaires

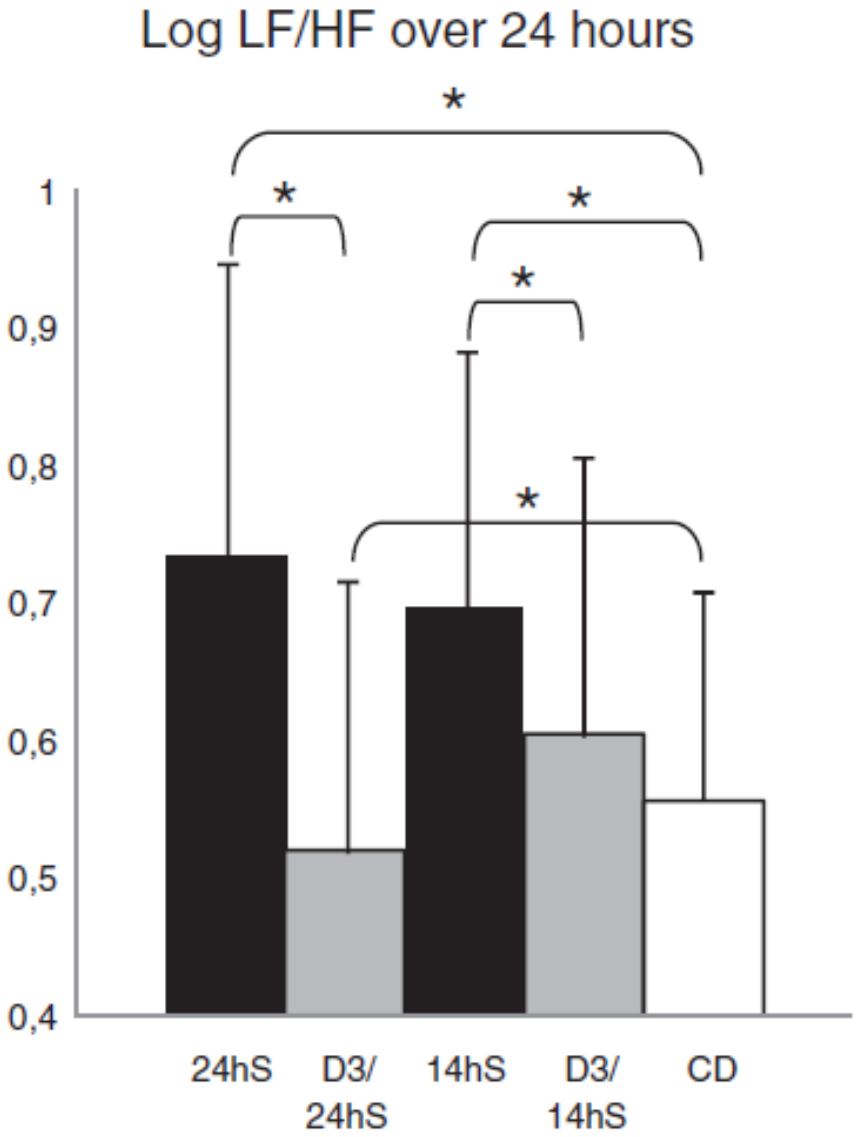
JOBSTRESS study

Visual Analog Scale



JOBSTRESS study

Stress Biomarkers: HRV



JOBSTRESS study

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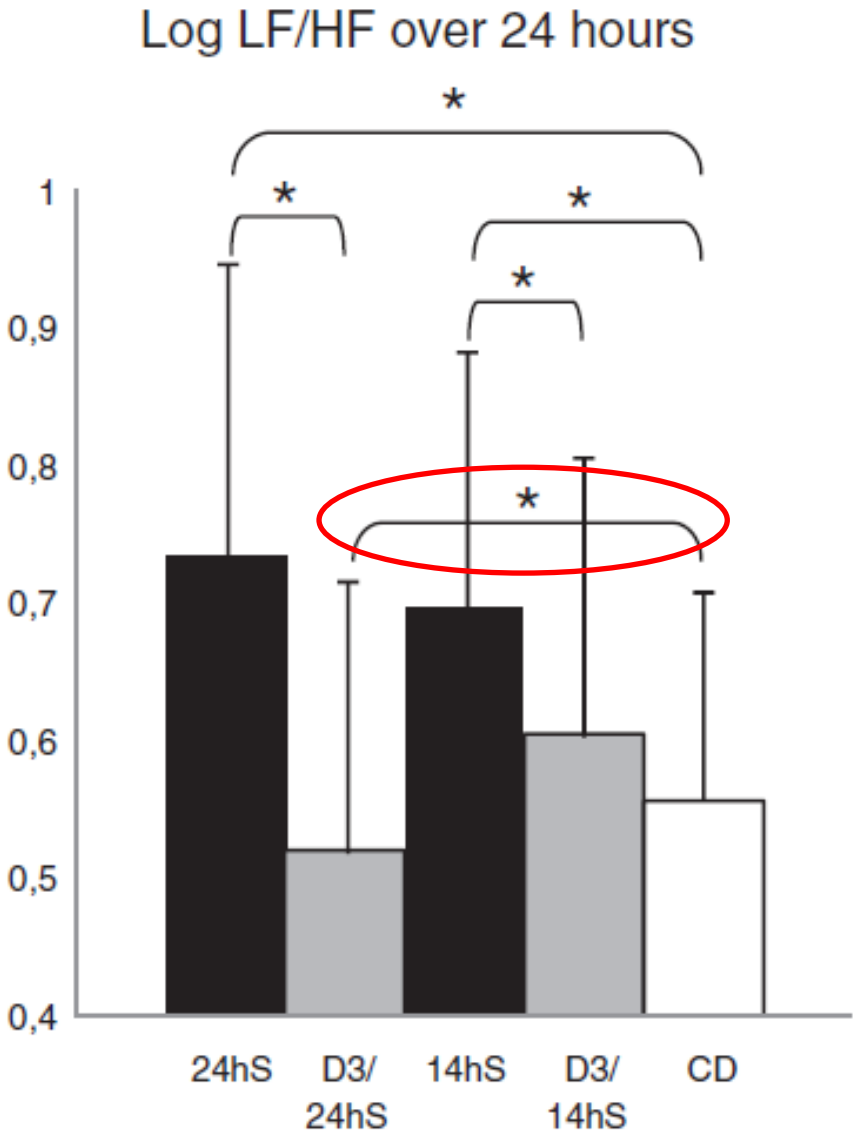
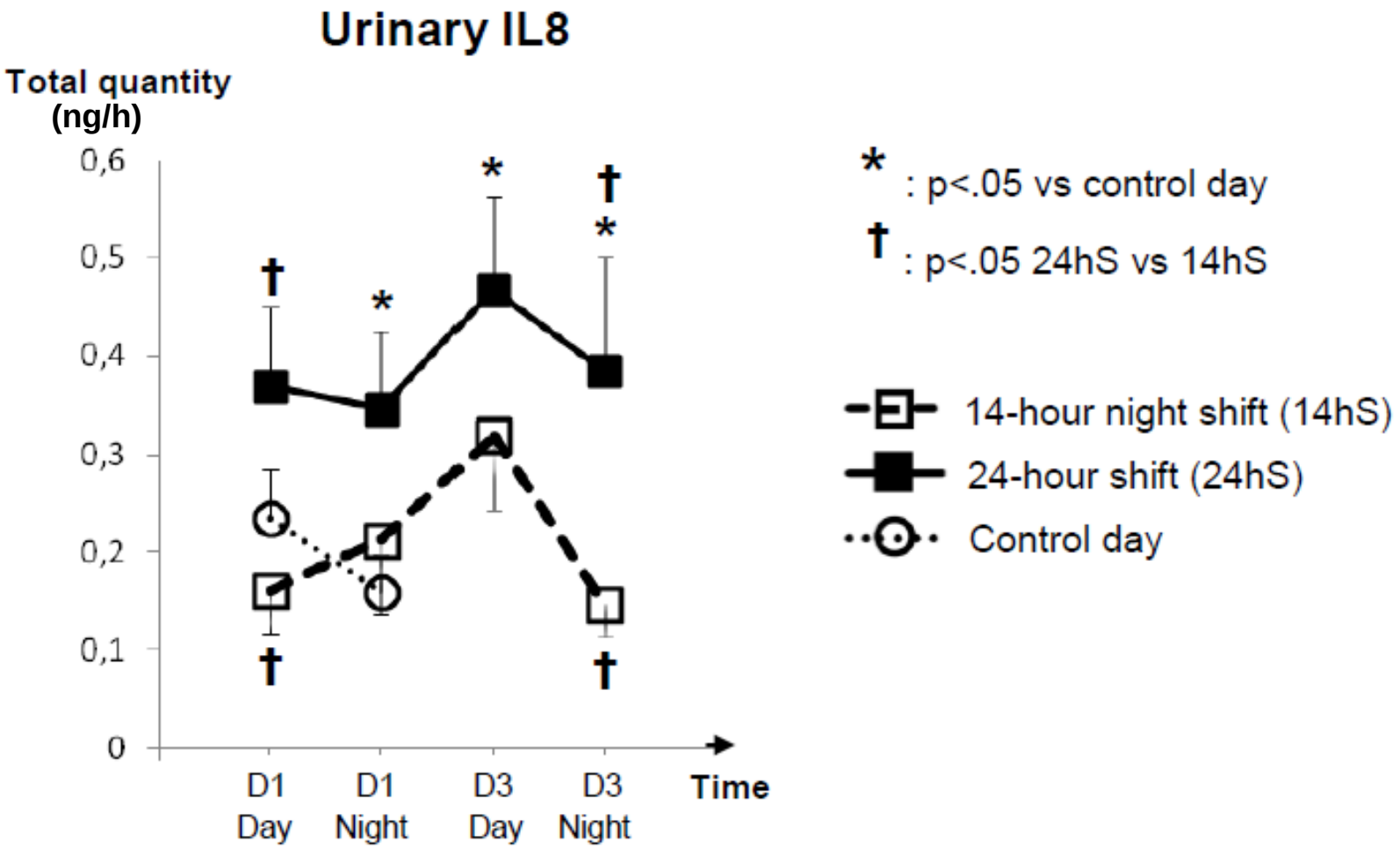


JOBSTRESS study

Urinary Stress Biomarkers



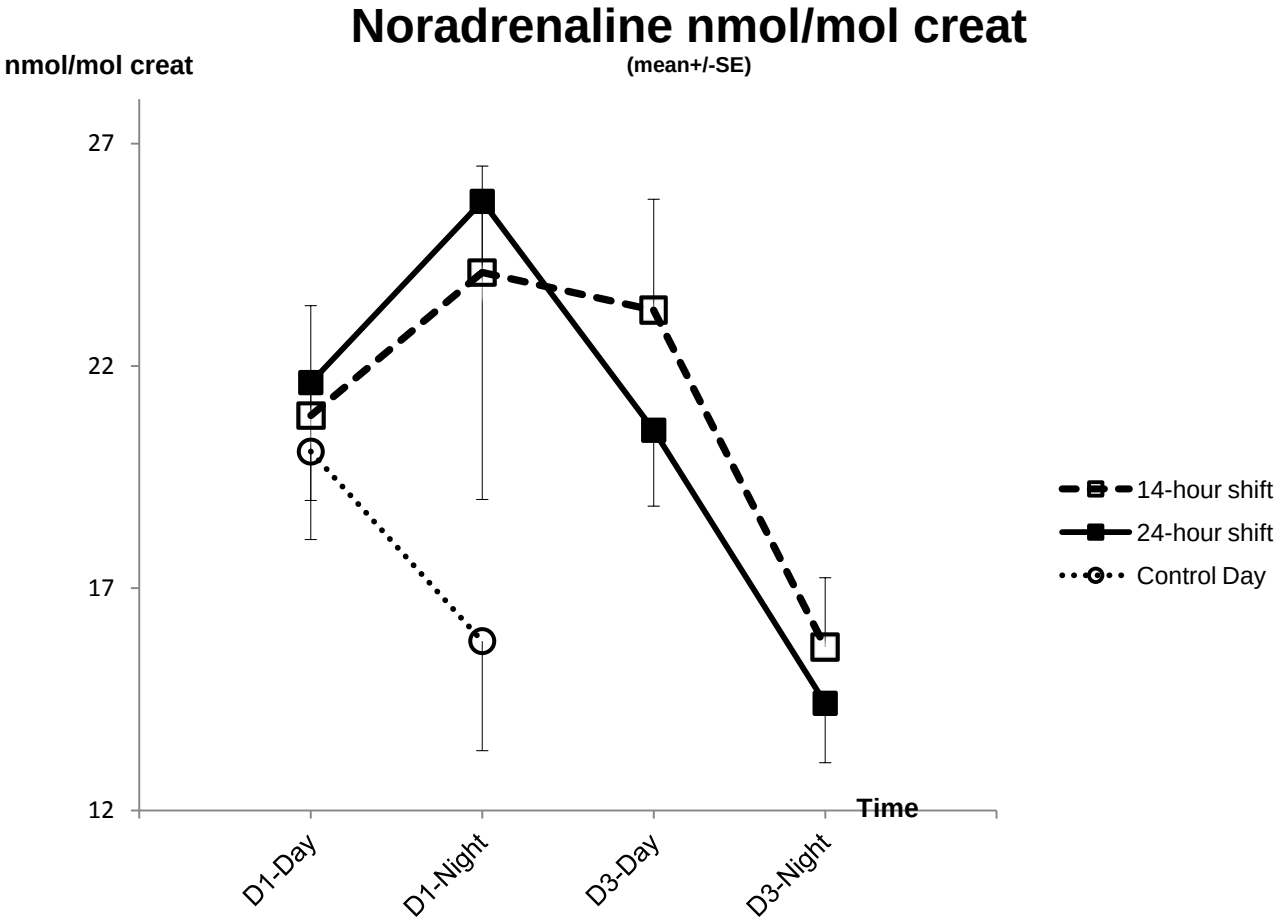
JOBSTRESS study

Urinary Stress Biomarkers

DOPA → NorAd → Ad

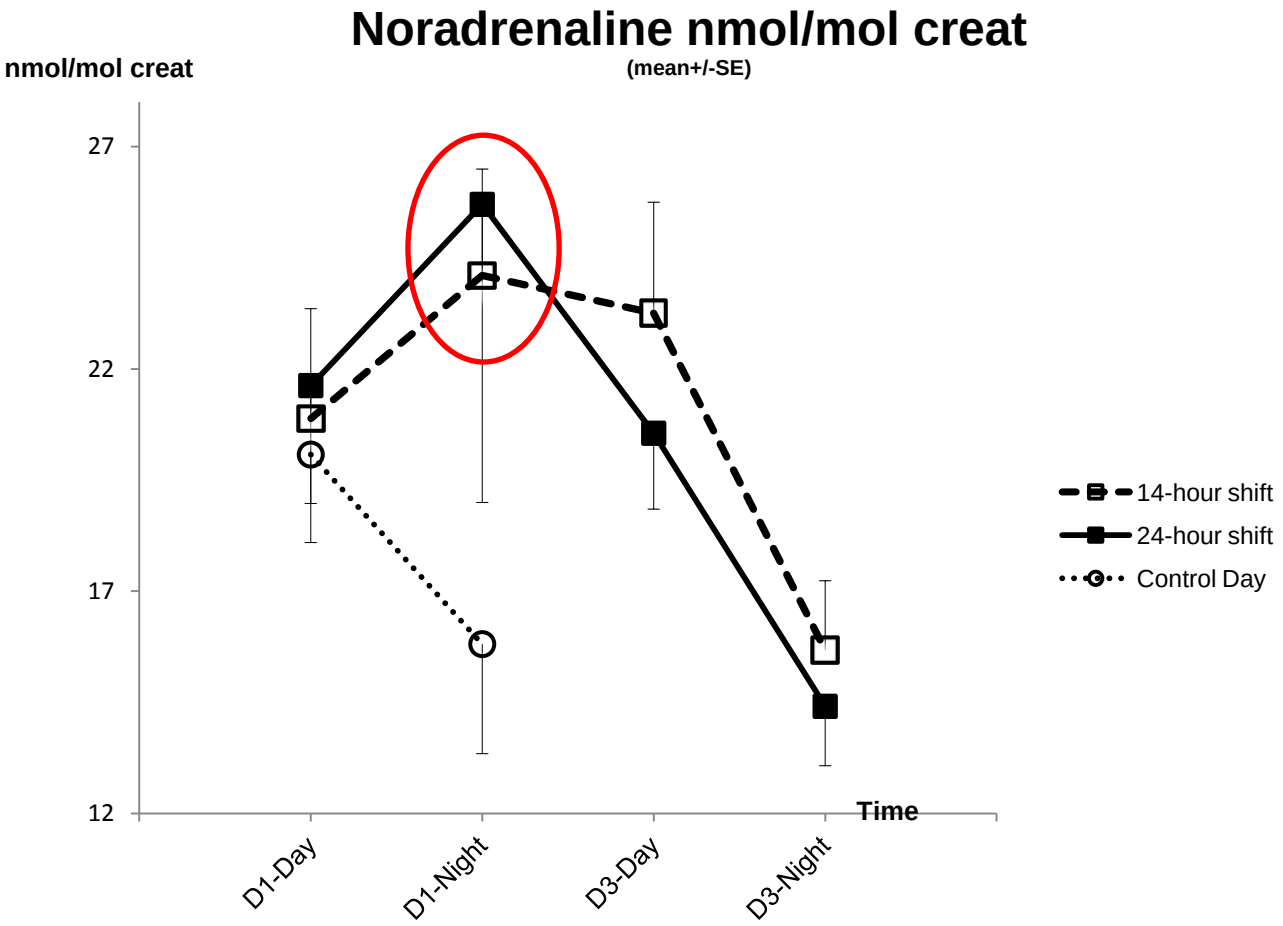
JOBSTRESS study

Biomarqueurs de stress



JOBSTRESS study

Biomarqueurs de stress



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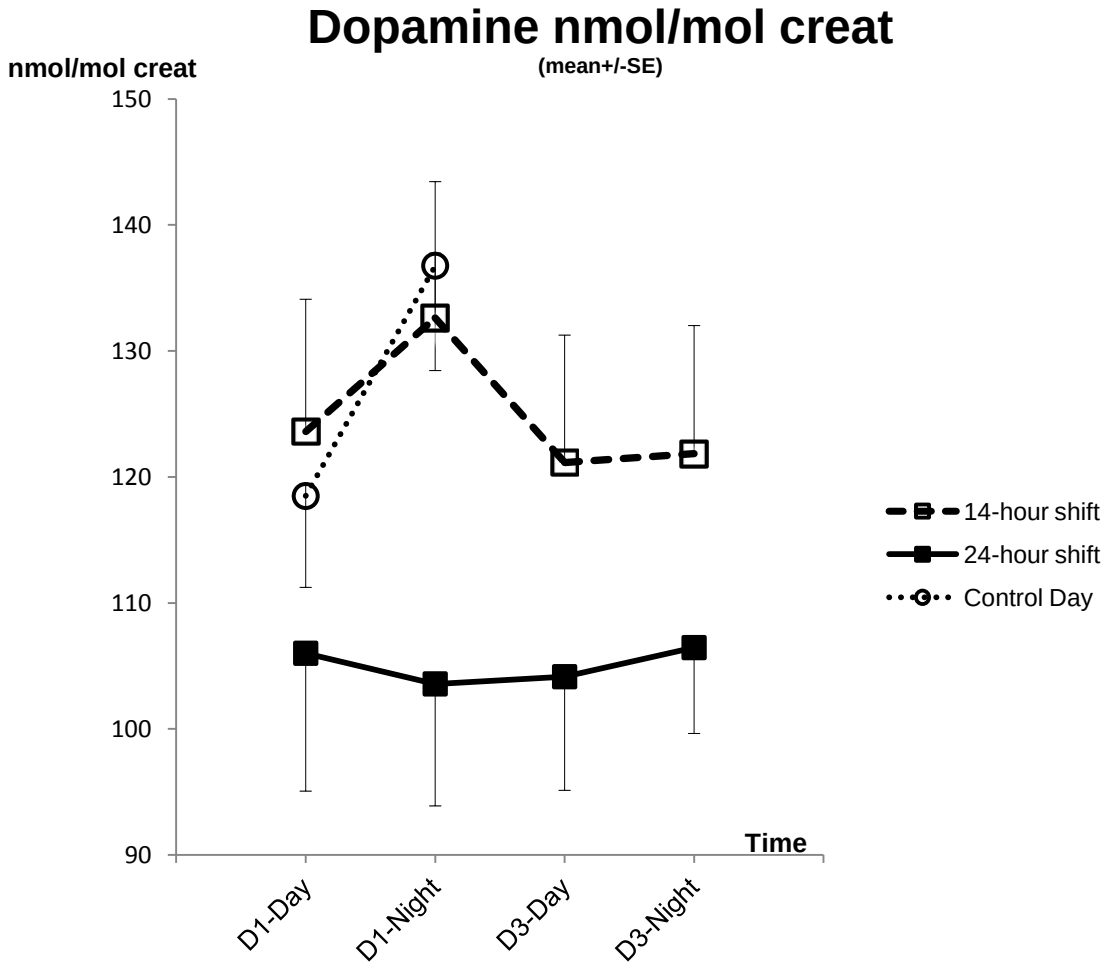

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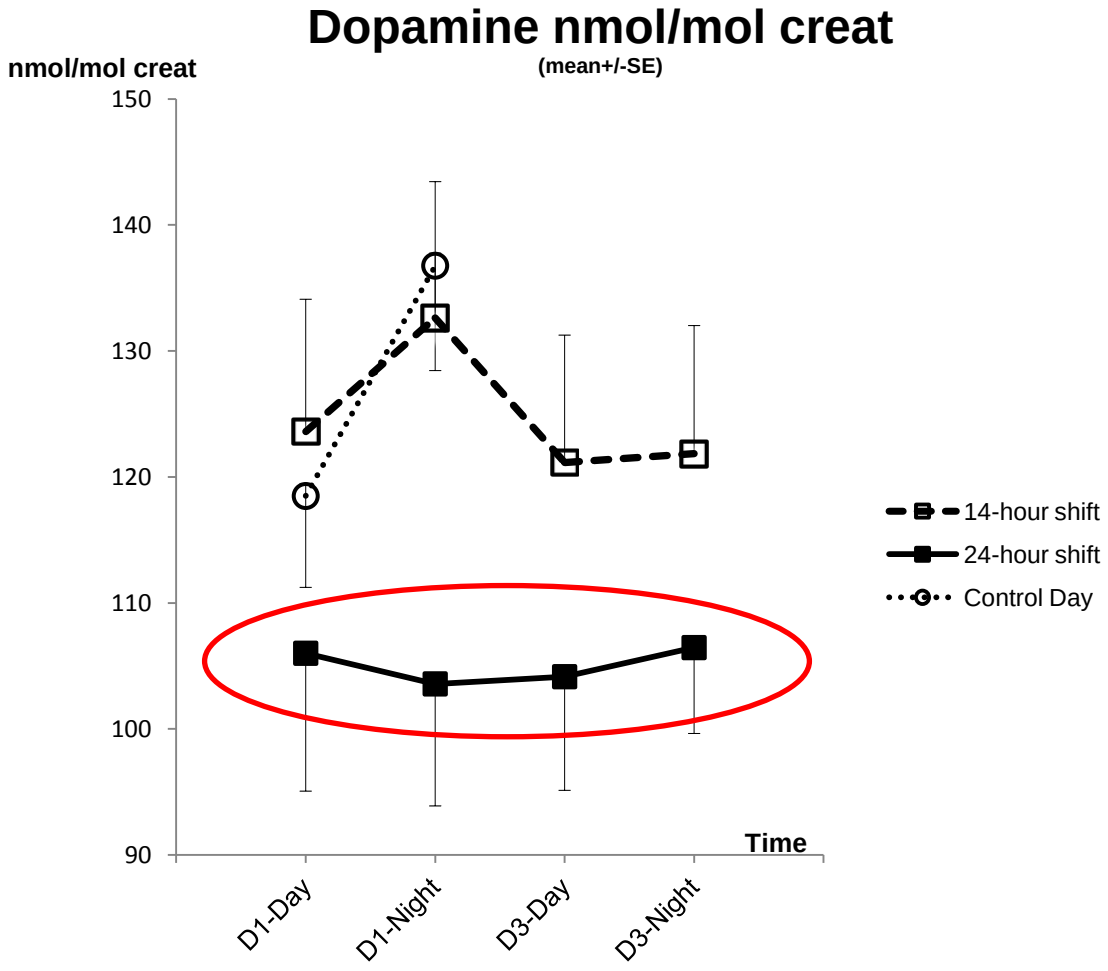

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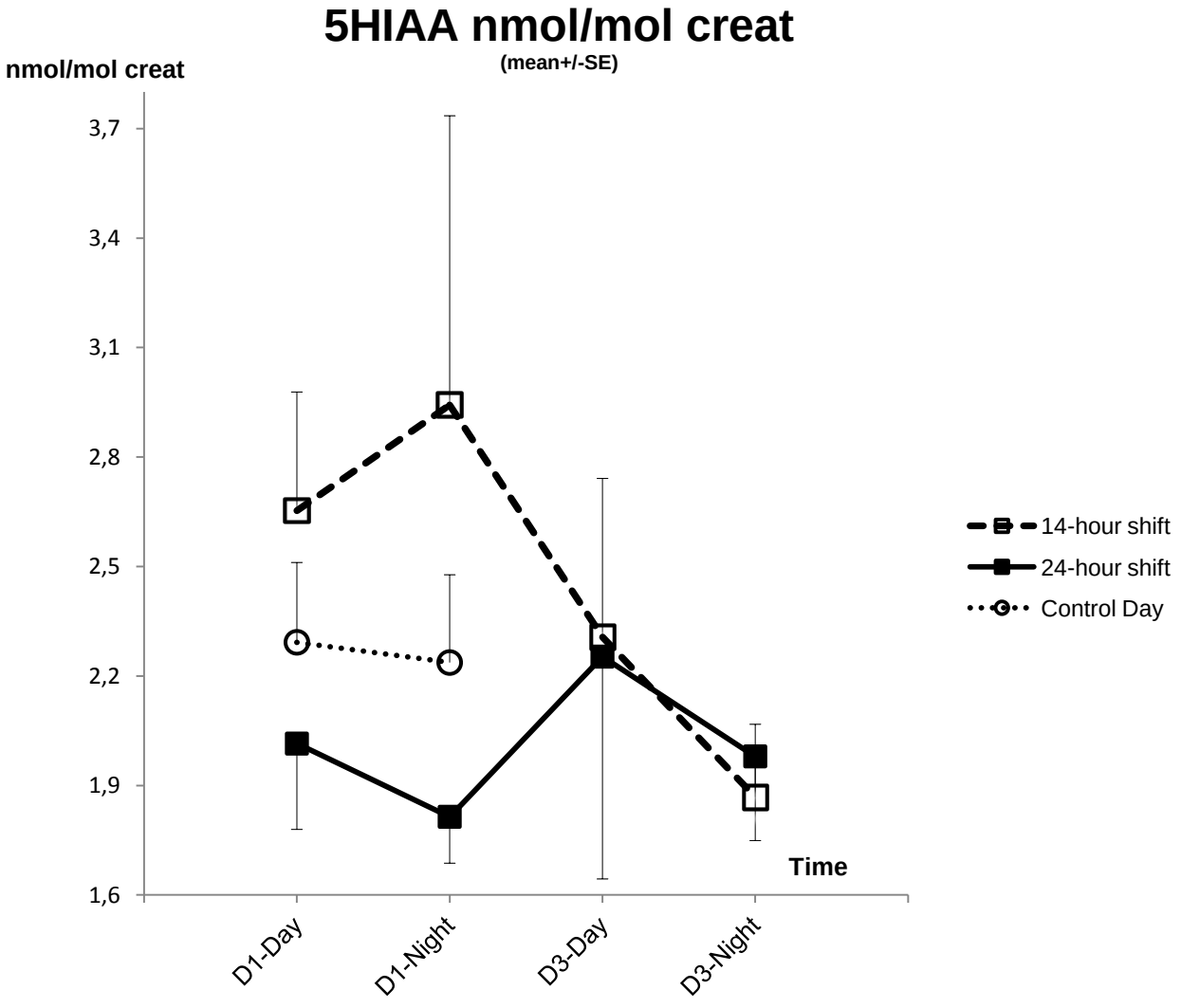

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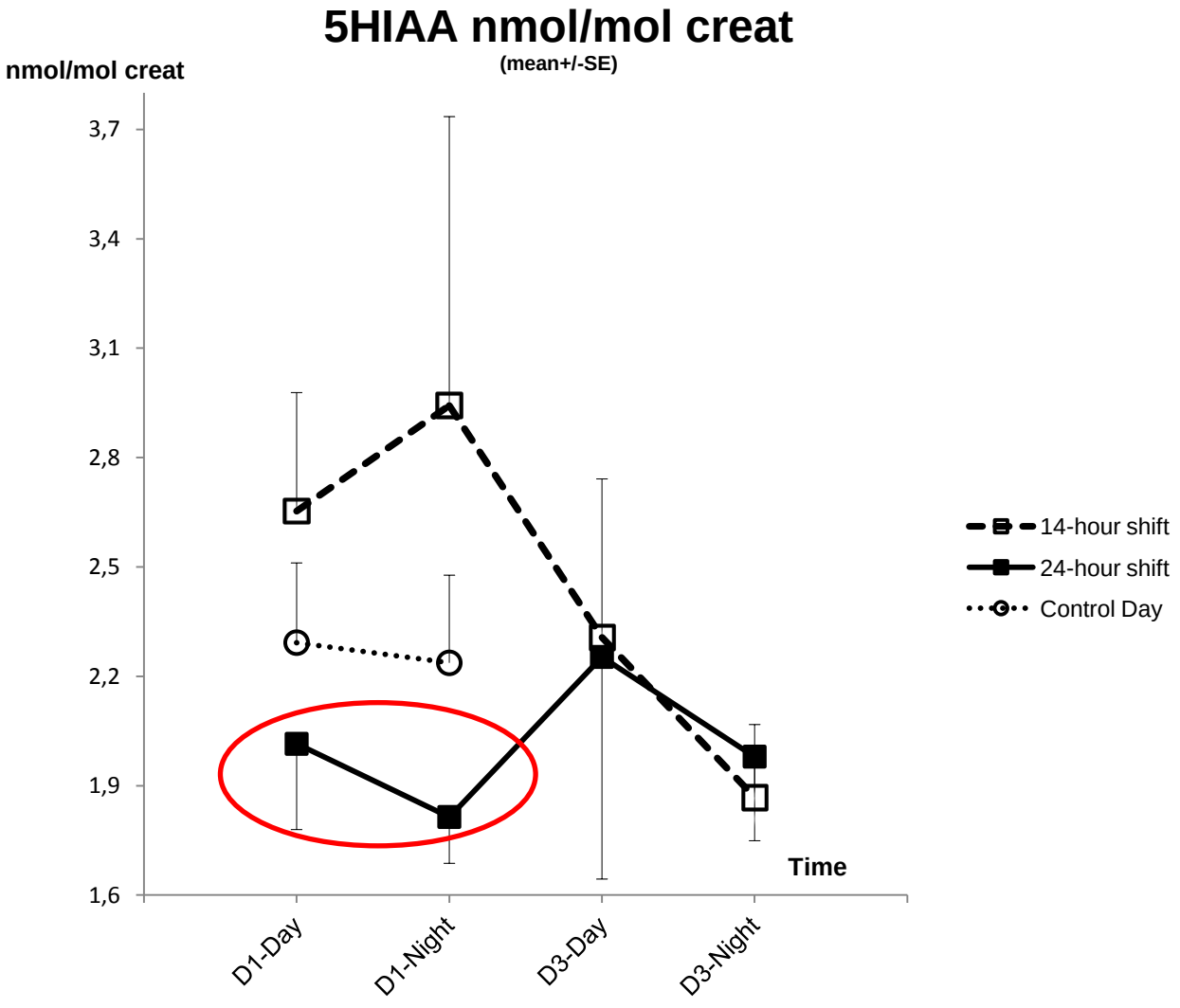

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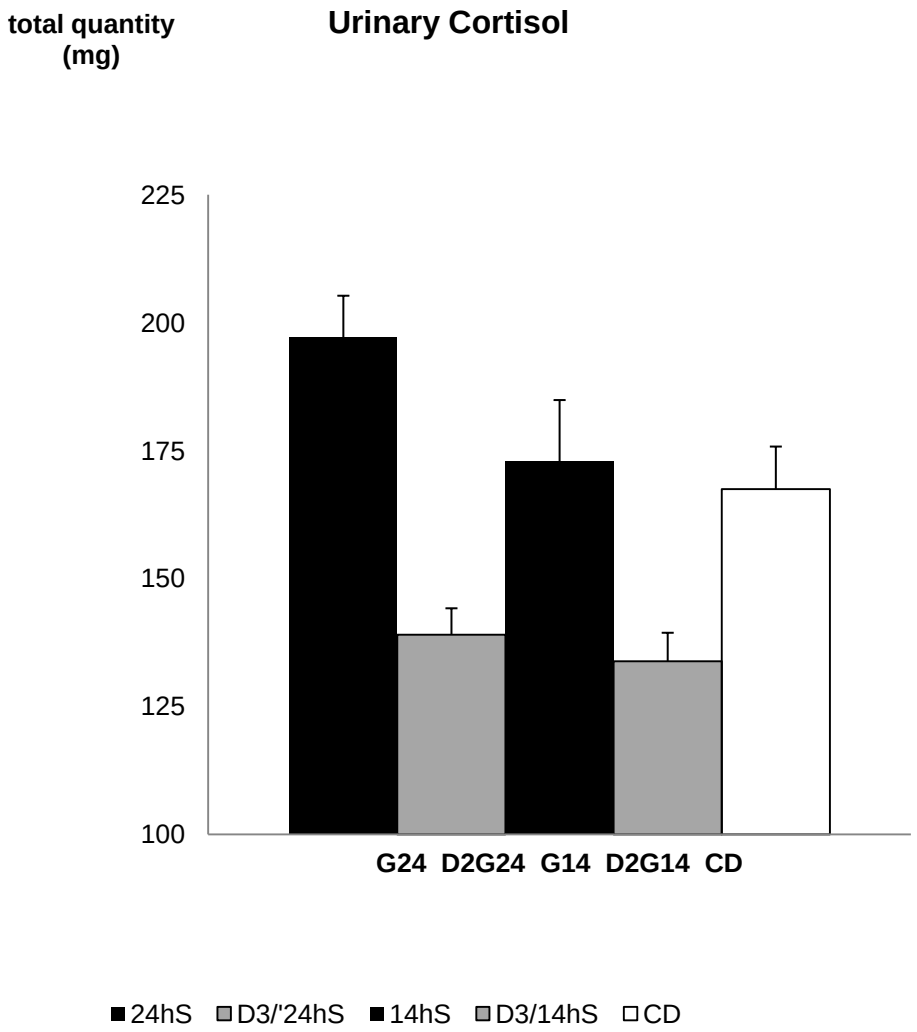

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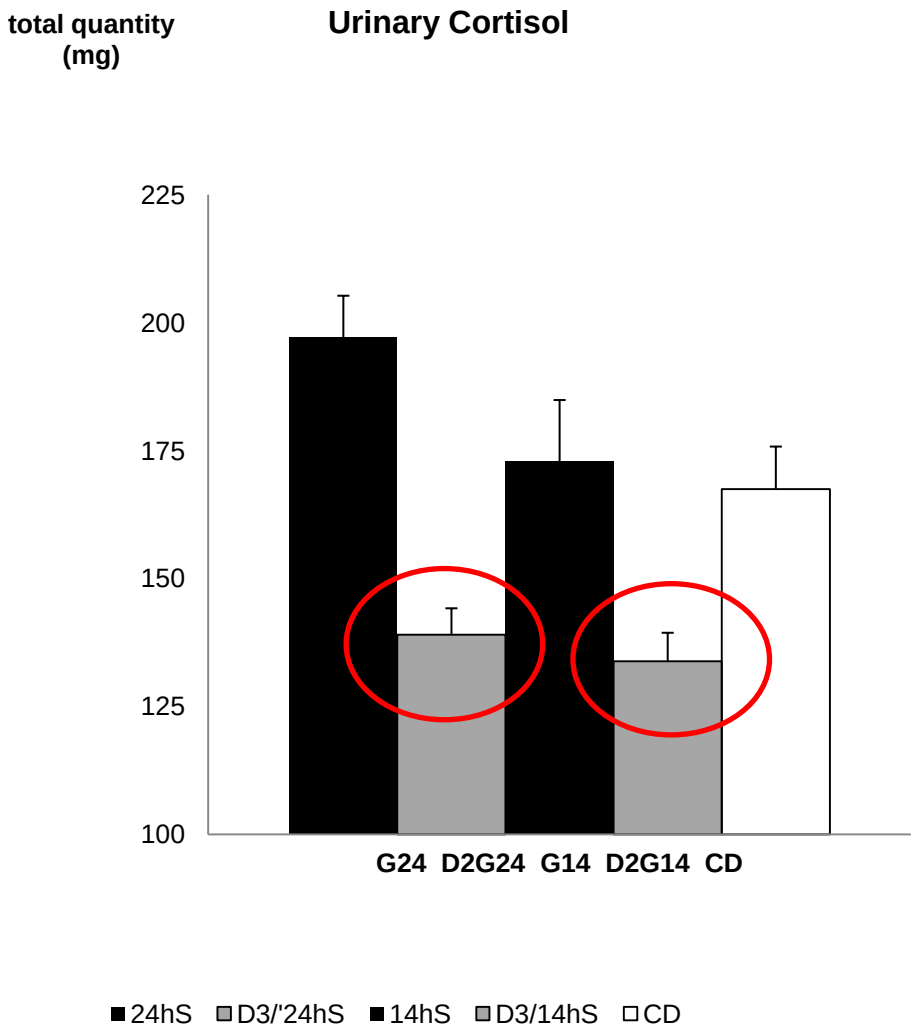
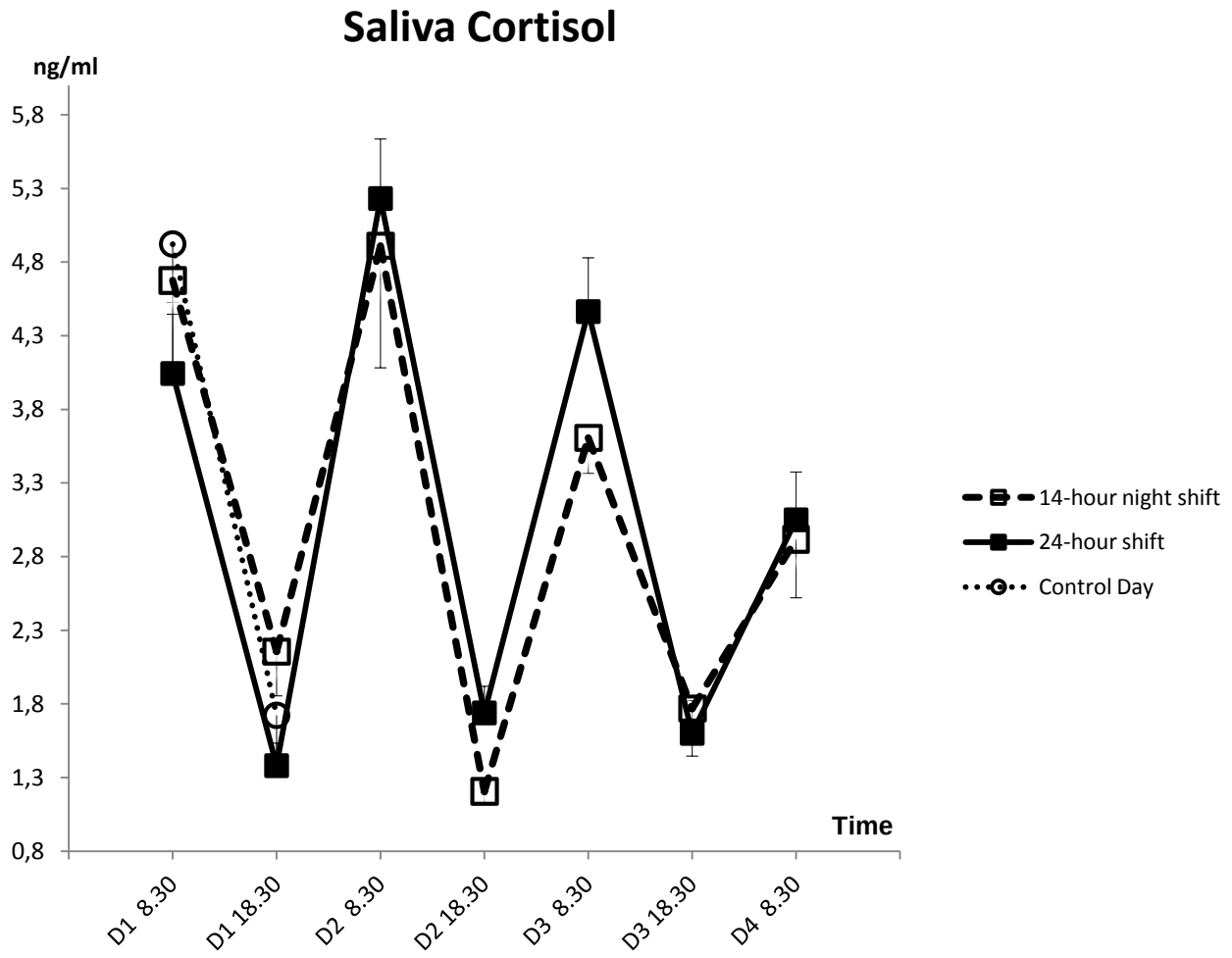


JOBSTRESS study

Stress Biomarkers in saliva



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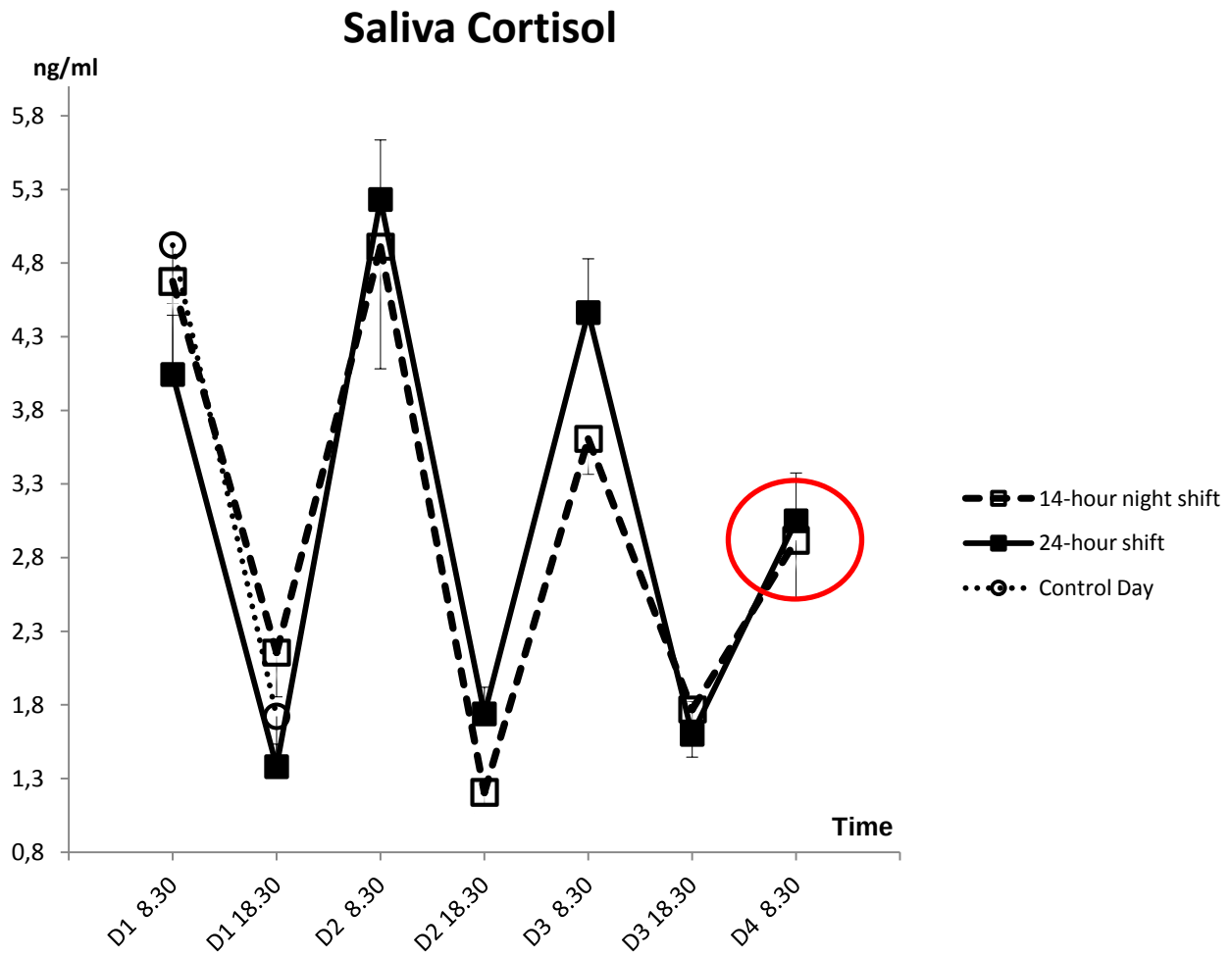

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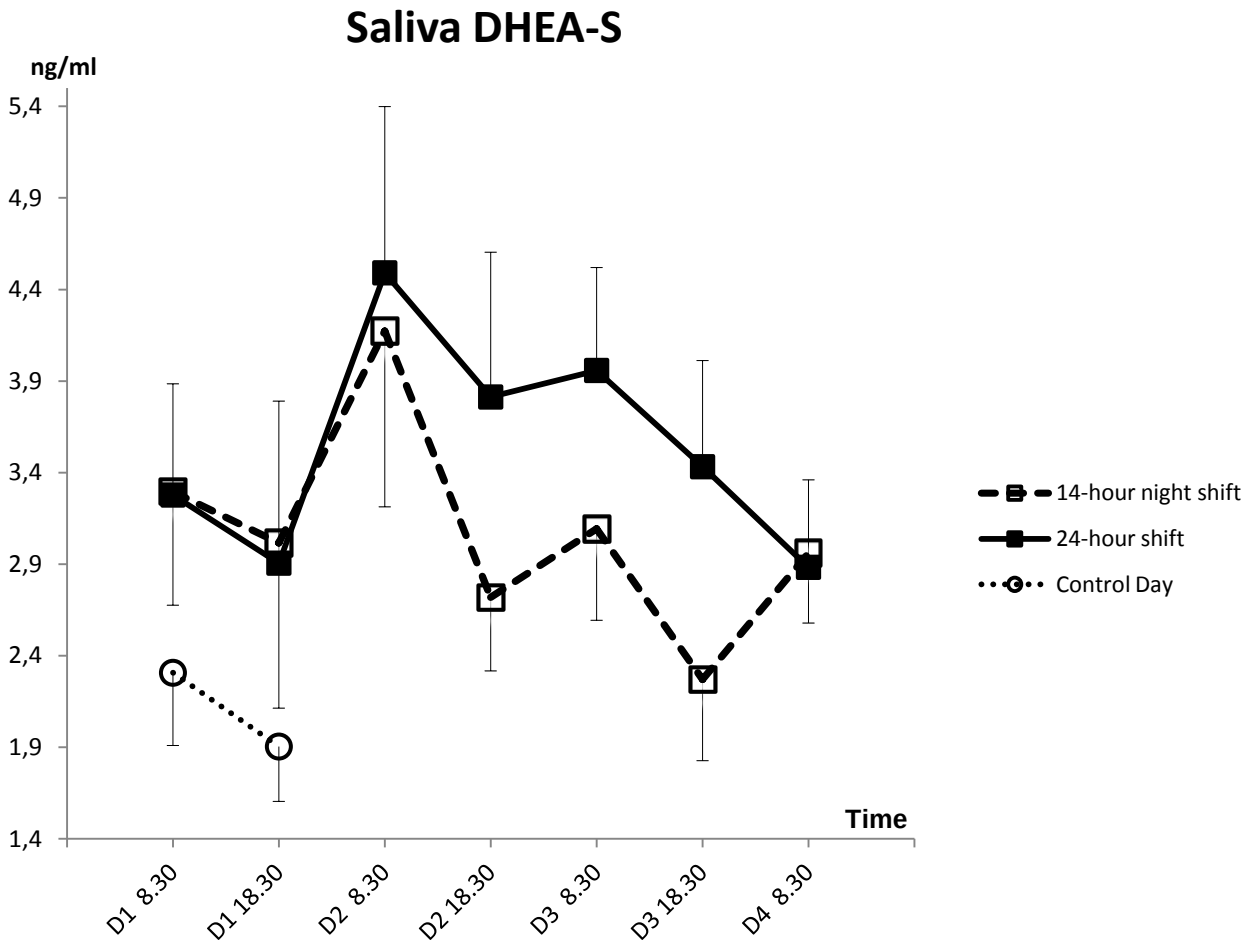

Stress Biomarkers

- 500 euros/80 dosages

J Neuroendocrinol. 2011 May;23(5):450-5. doi: 10.1111/j.1365-2826.2011.02118.x.
Age-related changes in plasma dehydroepiandrosterone levels in adults with Down's syndrome and the risk of dementia.
Landt J, Ball SL, Holland AJ, Hon J, Owen A, Treppner P, Herbert J.

Neurosci Lett. 2006 Oct 9;406(3):298-302. Epub 2006 Aug 22.
Bioavailable estradiol and age at onset of Alzheimer's disease in postmenopausal women with Down syndrome.
Schupf N, Winsten S, Patel B, Pang D, Ferin M, Zigman WB, Silverman W, Mayeux R.

Int J Gynaecol Obstet. 1999 Oct;67(1):15-21.
Gonadal function in young women with Down syndrome.
Angelopoulou N, Souftas V, Sakadamis A, Matziari C, Papameletiou V, Mandroukas K.

WHO approved registry: why? How?

What is PLoS Medicine's policy on trials registration?

By Emma Veitch
Posted: February 18, 2011

It's now well over five years since the International Committee of Medical Journal Editors announced a policy requiring that clinical trials considered for publication in its journals must have been previously registered in a public database. This policy was originally intended to promote greater transparency in

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WHO approved registry: why? How?

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- Brazilian Clinical Trials Registry (ReBec)
- Chinese Clinical Trial Registry (ChiCTR)
- Clinical Research Information Service (CRiS), Republic of Korea
- Clinical Trials Registry - India (CTRI)
- Cuban Public Registry of Clinical Trials(RPCEC)
- EU Clinical Trials Register (EU-CTR)
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- …

ClinicalTrials.gov (NCT)

WHO approved registry: why? How?

ClinicalTrials.gov
Protocol Registration System

Title IND Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links

Title:	

Unique Protocol ID:	
Brief Title:	
Official Title:	
Secondary ID's: (*One ID per line*) Definition: Other identification numbers assigned to the protocol, including any applicable NIH grant numbers. Provide up to 5 Secondary ID Numbers. Example: NCI-793-0115D	

WHO approved registry: why? How?

Purpose: Reason for the protocol	
Allocation: Participant selection • **Nonrandomized Trial**: participants are expressly assigned to intervention groups	
Masking: knowledge of intervention assignments • **Open**: no masking is used. All involved know the identity of the intervention assignment.	
Control: Nature of the intervention control • **Uncontrolled**: no controls are used	

RE: clinical trial.gov Ma

De Paquet Virginie

À Frédéric Dutheil perso

Bonjour Monsieur,

Nous avons ENFIN le n° d'enregistrement pour votre étude : **NCT 01874704**.

Bonne journée.

Cordialement.

Virginie PAQUET

Délégation à la Recherche Clinique et à l'Innovation

CHU de Clermont-Ferrand

Villa annexe IFSI

58 rue Montalembert

63003 Clermont-Ferrand cedex

WHO approved registry: why? How?

- http://clinicaltrials.gov/

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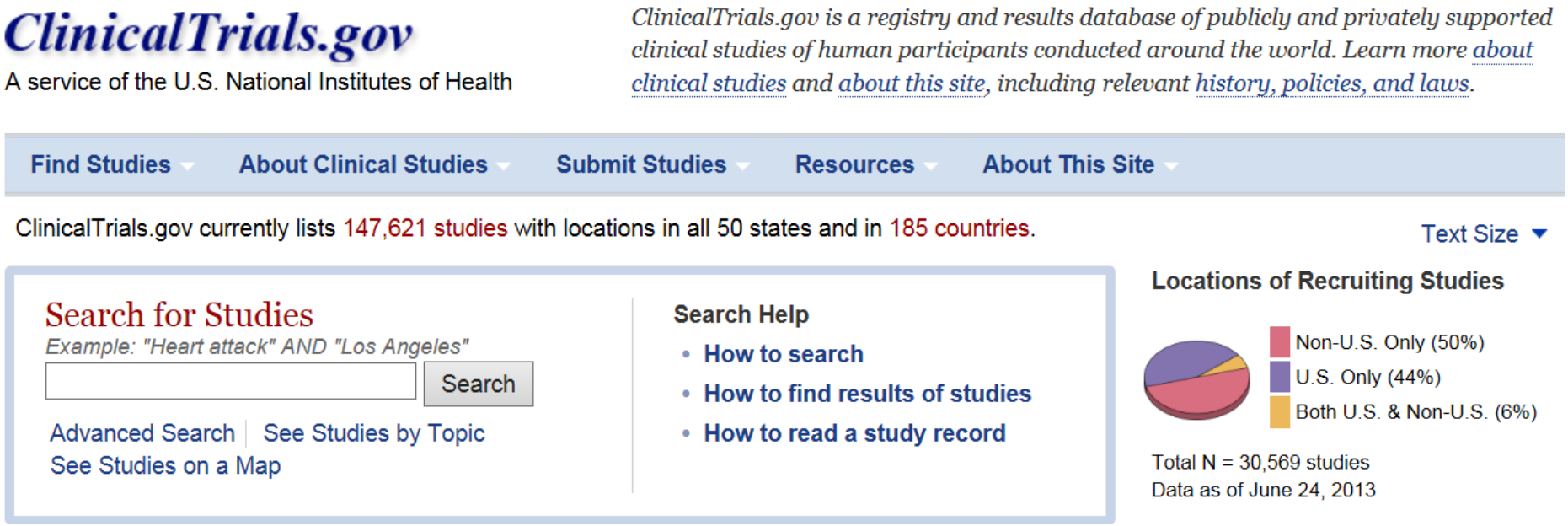

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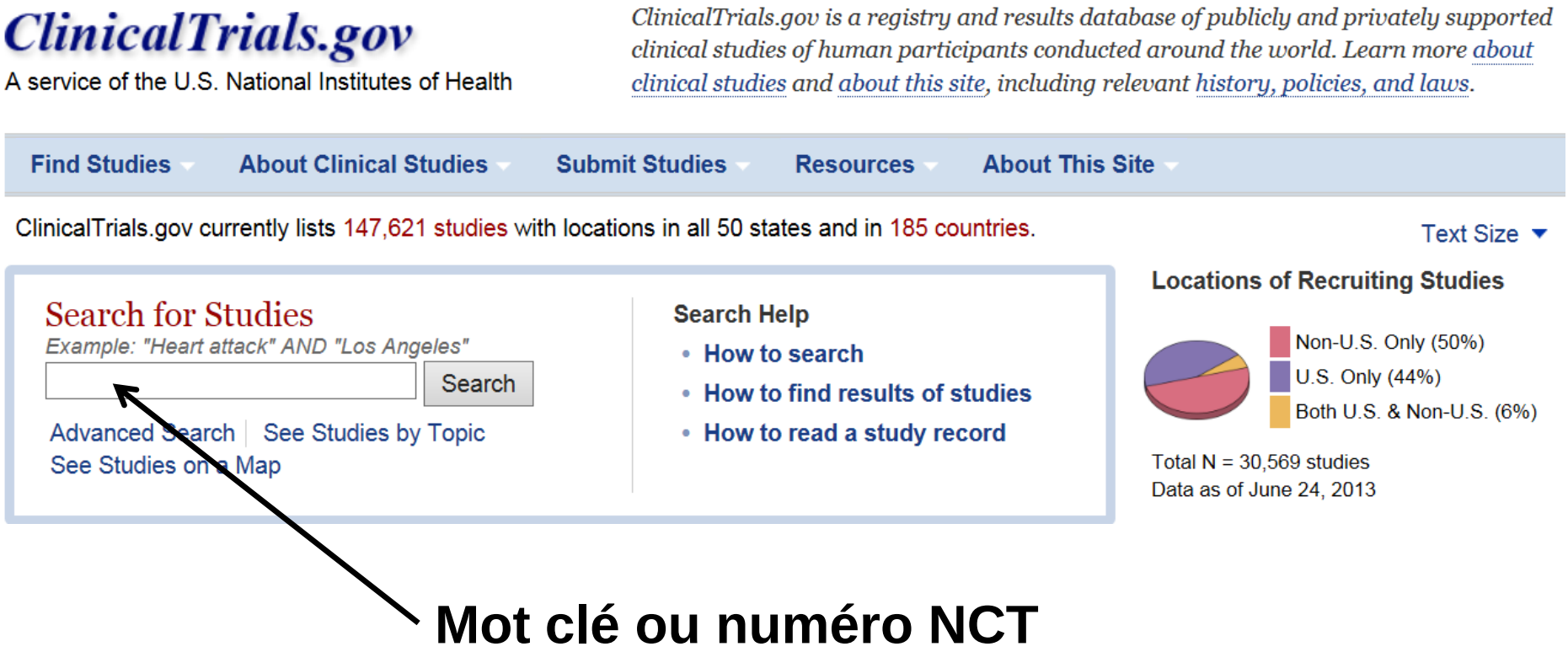

WHO approved registry: why? How?

Mot clé = psychologie

Rank	Status	Study
1	Enrolling by invitation	Positive Psychology for Mood Disorders **Conditions:** Bipolar Disorder; Depression **Interventions:** Behavioral: Positive psychology intervention; Beha
2	Completed	Development of a Positive Psychology Intervention to Reduce Suicide Risk **Conditions:** Suicidal Ideation; Suicide Attempt **Intervention:** Other: Positive Psychology Exercises
3	Completed	Mind-body Interventions in Cardiac Patients **Conditions:** Acute Coronary Syndrome; Congestive Heart Failu **Interventions:** Other: Positive Psychology; Behavioral: Relaxatior
4	Enrolling by invitation	The Impact of a Bariatric Rehabilitation Service on Patient Outcomes **Conditions:** Obesity; Bariatric Surgery Candidate

Effects of Diet and Physical Activity Interventions on Weight Loss and Cardiometabolic Risk Factors in Severely Obese Adults:

A Randomized Trial

Dr. Bret H. Goodpaster, PhD, **Dr. James P. DeLany, PhD**, **Dr. Amy D. Otto, PhD**, **Dr. Lewis Kuller, MD**, **Dr. Jerry Vockley, MD, PhD**, **Dr. Jeannette E. South-Paul, MD**, **Dr. Stephen B. Thomas, PhD**, **Dr. Jolene Brown, MD**, **Dr. Kathleen McTigue, MD, MS, MPH**, **Dr. Kazanna C. Hames, MS**, **Dr. Wei Lang, PhD**, and **Dr. John M. Jakicic, PhD**

Divisions of Endocrinology and Metabolism (Goodpaster, DeLany, and Brown and Ms Hames) and General Internal Medicine (Dr McTigue), Department of Medicine, and Departments of Pediatrics (Dr Vockley) and Family Medicine (Dr South-Paul), School of Medicine, University of Pittsburgh, Pittsburgh, Pennsylvania; Physical Activity and Weight Management Research Center, Department of Health and Physical Activity, University of Pittsburgh (Drs Otto and Jakicic and Ms Hames); Departments of Epidemiology (Dr Kuller), Human Genetics (Dr Vockley), and Behavioral and Community Health Sciences (Dr Thomas), University of Pittsburgh Graduate

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Corresponding Author: Bret H. Goodpaster, PhD, Division of Endocrinology and Metabolism, Department of Medicine, School of Medicine, University of Pittsburgh, MUH N810, 3459 Fifth Ave, Pittsburgh, PA 15213 (bgood@pitt.edu).

Trial Registration clinicaltrials.gov Identifier: NCT00712127

Author Contributions: Dr Goodpaster had full access to all of the data in the study and takes responsibility for the integrity of the

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A B S T R A C T

Background: Opinions differ over the exercise modalities that best limit cardiovascular risk (CVR) resulting from visceral obesity in individuals with metabolic syndrome (MetS). As little is known about the combined effects of resistance and endurance training at high volumes under sound nutritional conditions, we aimed to analyze the impact of various intensities of physical activity on visceral fat and CVR in individuals with MetS.
Methods: 100 participants, aged 50–70 years, underwent a diet restriction (protein intake 1.2 g/kg/day) with a high exercise volume (15–20 h/week). They were randomized to three training groups: moderate-resistance–moderate-endurance (re), high-resistance–moderate-endurance (Re), or moderate-resistance–high-endurance (rE). A one-year at-home follow-up (M12) commenced with a three-week residential program (Day 0 to Day 21). We measured the change in visceral fat and body composition by DXA, MetS parameters, fitness, the Framingham score and carotid-intima–media-thickness.
Results: 78 participants completed the program. At D21, visceral fat loss was highest in Re (−18%, $p < .0001$) and higher in rE than re (−12% vs. −7%, $p < .0001$). Similarly, from M3, visceral fat decreased more in *high-intensity-groups* to reach a visceral fat loss of −21.5% (Re) and −21.1% (rE) > −13.0% (re) at M12 ($p < .001$). CVR, MetS parameters and fitness improved in all groups. Visceral fat loss correlated with changes in MetS parameters.
Conclusion: Increased intensity in high volume training is efficient in improving visceral fat loss and carotid-intima–media-thickness, and is realistic in community dwelling, moderately obese individuals. High-intensity-resistance training induced a faster visceral fat loss, and thus the potential of resistance training should not be undervalued (ClinicalTrials.gov number: NCT00917917).

ABSTRACT

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Stratégie de publication: Trials

Home | Articles | Authors | Reviewers | About this journal

Trials is an open access, peer-reviewed, online journal that encompasses all aspects of the performance and findings of randomized controlled trials. We publish articles on general trial methodology as well as protocols, commentaries and traditional results papers - regardless of outcome or significance of findings.

Editors-in-Chief

Doug Altman, University of Oxford

Curt Furberg, Wake Forest University of Medicine

Jeremy Grimshaw, Ottawa Health Research Institute

Peter Rothwell, University of Oxford

Editorial Board | Instructions for authors | FAQ

Trials

BioMed Central

Study protocol

Open Access

Double blind randomized placebo-controlled trial on the effects of testosterone supplementation in elderly men with moderate to low testosterone levels: design and baseline characteristics

Abstract

In ageing men testosterone levels decline, while cognitive function, muscle and bone mass, sexual hair growth, libido and sexual activity decline and the risk of cardiovascular diseases increase. We set up a double-blind, randomized placebo-controlled trial to investigate the effects of testosterone supplementation on functional mobility, quality of life, body composition, cognitive function, vascular function and risk factors, and bone mineral density in older hypogonadal men.

We recruited 237 men with serum testosterone levels below 13.7 nmol/L and ages 60–80 years. They were randomized to either four capsules of 40 mg testosterone undecanoate (TU) or placebo daily for 26 weeks. Primary endpoints are functional mobility and quality of life. Secondary endpoints are body composition, cognitive function, aortic stiffness and cardiovascular risk factors and bone mineral density. Effects on prostate, liver and hematological parameters will be studied with respect to safety.

Measure of effect will be the difference in change from baseline visit to final visit between TU and placebo. We will study whether the effect of TU differs across subgroups of baseline waist girth (< 100 cm vs. ≥ 100 cm; testosterone level (<12 versus ≥ 12 nmol/L), age (< median versus ≥ median), and level of outcome under study (< median versus ≥ median).

Results: 10

1. Low testosterone concentrations and the symptoms of testosterone deficiency according to the Androgen Deficiency in Ageing Males (ADAM) and Ageing Males' Symptoms rating scale (AMS) questionnaires.

   Emmelot-Vonk MH, Verhaar HJ, **Nakhai-Pour HR**, Grobbee DE, **van der Schouw YT**.
   Clin Endocrinol (Oxf). 2011 Apr;74(4):488-94. doi: 10.1111/j.1365-2265.2010.03954.x.
   PMID: 21138462 [PubMed - indexed for MEDLINE]
   Related citations

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