# Effectiveness of sleeping device to keeping children in position while riding motor vehicles

<b>Submission date</b> 07/02/2011	<b>Recruitment status</b> No longer recruiting	<ul> <li>Prospectively registered</li> <li>Protocol</li> </ul>
<b>Registration date</b> 07/04/2011	<b>Overall study status</b> Completed	<ul> <li>Statistical analysis plan</li> <li>Results</li> </ul>
Last Edited 08/04/2011	<b>Condition category</b> Other	<ul> <li>Individual participant data</li> <li>Record updated in last year</li> </ul>

## Plain English summary of protocol

Not provided at time of registration

## **Contact information**

**Type(s)** Scientific

**Contact name** Dr Maria Segui-Gomez

### Contact details

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers N/A

## Study information

#### Scientific Title

Effectiveness of sleeping device to keeping children in position while riding motor vehicles: a non-blinded single centre controlled crossover interventional randomised trial

#### Study objectives

A new (copyrighted) sleeping device will allow children to maintain head, neck and torso in position while asleep during travel, therefore reducing the chances of out of position (OOP) risky behaviors

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** University of Navarra Ethics Committee pending as of 22/02/2011

**Study design** Single centre randomised controlled unblinded crossover intervention trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Other

**Study type(s)** Quality of life

#### Participant information sheet

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

Health condition(s) or problem(s) studied Sleeping position

#### Interventions

Comparator: Regular sleeping aids (if any): pillows, blankets, folded clothing, stuffed animal, etc., anything the child regularly uses when travelling to make him/herself more comfortable.

#### Intervention:

Siesta System sleeping device, a head suspender device that mimicks the concept of a hammock. The device is copyrighted and patented.

Intervention Type

Device

**Phase** Not Applicable

#### Primary outcome measure

Percent of the travel time in which the child in out of position as observed by markers placed and recorded with a triaxial camera system that records all the travel.

**Secondary outcome measures** No secondary outcome measures

Overall study start date 01/09/2010

Completion date

01/03/2011

# Eligibility

#### Key inclusion criteria

1. Children ages 7-12 (inclusive) 2. Either sex 3. Maximum height 150 cm

**Participant type(s)** Patient

**Age group** Child

**Lower age limit** 7 Years

**Upper age limit** 12 Years

**Sex** Both

**Target number of participants** 30

#### Key exclusion criteria

- 1. Acute disease at time of experiment
- 2. Children with travel sickness
- 3. Morbidly obese children
- 4. Children with behavioural issues that would make it difficult collaborating in the experiment

5. Does not match inclusion criteria

#### Date of first enrolment

01/09/2010

Date of final enrolment 01/03/2011

## Locations

**Countries of recruitment** Spain

**Study participating centre European Center for Injury Prevention** Pamplona Spain 31190

## Sponsor information

**Organisation** University of Navarra (Spain)

#### Sponsor details

c/o Javier Ferro European Center for Injury Prevention School of Medicine University of Navarra Irunlarrea 1 Pamplona Spain 31190

**Sponsor type** University/education

ROR https://ror.org/02rxc7m23

## Funder(s)

Funder type Industry **Funder Name** Developer of Siesta System

## **Results and Publications**

**Publication and dissemination plan** Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

**IPD sharing plan summary** Not provided at time of registration