

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Intentional

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

12 years

Sex

All

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)

ROR

<https://ror.org/02rxc7m23>

Funder(s)

Funder type

Industry

Funder Name

Developer of Siesta System

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration