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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Maria Segui-Gomez

Contact details
European Center for Injury Prevention
School of Medicine
University of Navarra
Ed. Castaños S200
Irunlarrea 1
Pamplona
Spain
31190

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