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# Arm Intervention After Stroke (AIAS): a feasibility study

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 07/07/2009 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 03/09/2009 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 15/07/2016 | Circulatory System | [ ] 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
GN09GE229 (Ethics no: 09/S0704/32)

# Study information

## Scientific Title
A randomised, feasibility, safety and efficacy of the ArmeoSpring arm orthosis for acute stroke patients with arm deficits

## Acronym
AIAS

## Study objectives
Arm rehabilitation provided by the ArmeoSpring is a feasible and acceptable intervention to implement with acute stroke patients with arm deficits.

Principal research question:
Is arm rehabilitaiton provided by the ArmeoSpring arm orthosis a feasible and acceptable intervention for acute stroke patients with arm deficits?

Secondary research questions:
1. Is arm rehabilitation provided by the ArmeoSpring arm orthosis, a safe intervention for acute stroke patients with arm deficits, compared with standard therapy?
2. What are the effects of two different intenstities of arm rehabilitaiton provided by the ArmeoSpring arm orthosis for acute stroke patients with arm deficits, compared with standard therapy?

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
West of Scotland (REC 4) Ethics Committee, 12/06/2009, ref: 09/S0704/32

## Study design
Single-blind single-centre randomised feasibility/pilot study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## 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

Acute stroke

## Interventions
The participants will be randomly allocated to one of the three following arms:
1. Standard care: usual therapy, provided by physiotherapists and occupational therapists
2. ArmeoSpring arm orthosis intervention 1: 40 minutes, 3 times a week, in addition to standard care
3. ArmeoSpring arm orthosis intervention 2: 60 minutes, 5 times a week, in addition to standard care

Total duration of interventions: 2 weeks or discharge (whichever is sooner)
Total duration of follow-up: 3 months
ArmeoSpring intervention will be delievered by a research therapist.

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
1. Feasibility of experimental interventions:
1.1. Number of per protocol interventions recorded at end of intervention period
1.2. Reasons for non-compliance recorded at end of intervention period
2. Acceptability/satisfaction of experimental intervention: informal interviews with participants completed at the end of the intervention period

## Secondary outcome measures
Safety outcomes:
1. Arm pain (including shoulder) (measured by 5 point scale none-excruciating)
2. Shoulder subluxation (clinical report)
3. Fatigue (Borg perceived Exertion Scale)
4. All adverse events
Safety outcomes will be continously monitored and recorded throughout the study, however will be formally recorded at the end of the intervention period (2 weeks or discharge) (by clinical report and patient scales) and at 3 month report (by patient report and scales, on appropriate measures).

Efficacy outcomes:
1. Upper limb function: Action Research Arm Test
2. Upper limb impairment: Fugl-Meyer assessment (upper limb section)
3. Disability: Barthel Index

Exploratory outcome:
To assist in power calculation to determine the number of subjects required for a phase III randomised controlled trial.

## Overall study start date
03/08/2009

## Completion date

04/04/2010

# Eligibility

### Key inclusion criteria
1. Age greater than 18 years, either sex
2. Clinical diagnosis of stroke
3. Minimum grade 1 on MRC scale for arm impairment
4. Maximum grade 4 on MRC scale for arm impairment
5. Medically stable
6. Informed consent
7. Ability to understand and follow simple instructions
8. Sitting balance sufficent to use Armeo arm orthosis safely

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
18

### Key exclusion criteria
1. Orthosis cannot be fitted to affected limb
2. Bone instability of hemiparetic upper limb (fractures, severe arthritis)
3. Pre-exisiting upper limb deficits
4. Pronounced, fixed contractures of hemiparetic upper limb
5. Open skin lesions on hemiparetic upper limb
6. Major sensory deficit of hemiparetic upper limb
7. Shoulder instability or excessive pain
8. Severe spasticity
9. Severe spontaneous movements e.g. ataxia, dyskinesia
10. Confused or non-cooperative
11. Requiring isolation due to infection
12. Severe visual, perceptual or cognitive problems precluding participation in study protocol
13. Involved in any other intervention study

### Date of first enrolment
03/08/2009

### Date of final enrolment
04/04/2010

# Locations

### Countries of recruitment
Scotland

United Kingdom

### Study participating centre
**Academic Section of Geriatric Medicine**
Glasgow
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# Sponsor information

### Organisation
NHS Greater Glasgow and Clyde (UK)

### Sponsor details
Tennant Institute
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### Sponsor type
Government

### Website
http://www.nhsggc.org.uk

### ROR
https://ror.org/05kdz4d87

# Funder(s)

### Funder type
Government

**Funder Name**
Chief Scientist Office of the Scottish Executive Health Department (UK) (ref: CZF/07/12)

# 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