

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

<b>Submission date</b> 07/07/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 03/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/07/2016	<b>Condition category</b> Circulatory System	<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**  
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 rehabilitation 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 intensities of arm rehabilitation 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

## **Primary study design**

Interventional

## **Study design**

Single-blind single-centre randomised feasibility/pilot study

## **Study type(s)**

Treatment

## **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 delivered by a research therapist.

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

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

## **Key secondary outcome(s)**

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 continuously 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.

## **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 sufficient to use Armeo arm orthosis safely

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**Key exclusion criteria**

1. Orthosis cannot be fitted to affected limb
2. Bone instability of hemiparetic upper limb (fractures, severe arthritis)
3. Pre-existing 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**

United Kingdom

Scotland

**Study participating centre**

**Academic Section of Geriatric Medicine**

Glasgow

United Kingdom

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# Sponsor information

## Organisation

NHS Greater Glasgow and Clyde (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

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration