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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

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 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

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 delievered 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 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.

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

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-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
United Kingdom

Scotland

Study participating centre
Academic Section of Geriatric Medicine
Glasgow
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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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes