GFC Site Selection Questionnaire

Please complete the survey below.

If you have any questions do not hesitate to contact us.

AO Clinical Investigation and Documentation
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Thank you!

Hospital and Staff Contact Data Hospital address

Name of the hospital _____

Department (eg. Orthopeadics, Trauma, Surgery) _____

Address _____

Email _____

Phone _____

Fax _____

Principal Investigator PI (Qualified person responsible for conducting the clinical investigation at an investigation site)

Title, Name _____

Phone _____

Mobile _____

Email _____

Secretary

Title, Name _____

Phone _____

Mobile _____

Email _____

Which of the following staff/functions are available at your clinic?

Sub-Investigator SI (MD supporting the study at your clinic)
☐ Yes
☐ No

How many Sub-Investigators?
☐ 1
☐ 2
☐ 3

1) Title, Name _____

Phone _____

Mobile _____

Email _____

2) Title, Name _____

Phone _____

Mobile _____

Email _____

3) Title, Name _____

Phone _____

Mobile _____

Email _____

Study Coordinator SC / Research Nurse (Person responsible for study administration)
☐ Yes
☐ No

How many Study Coordinators / Research Nurses?
☐ 1
☐ 2
☐ 3

1) Title, Name _____

Phone _____

Mobile _____

Email _____

2) Title, Name _____

Phone _____

Mobile _____

Email _____

3) Title, Name _____

Phone _____

Mobile _____

Email _____

Clinical Trial unit

Access to clinical trial unit or similar

☐ Yes
☐ No

Clinical Trial Unit (or similar) contact details, if applicable: _____

Thank you for participating in this principal investigator and study site selection survey by AOCID. This survey will help to select the adequate study sites to perform this clinical investigation. Please review and answer all questions carefully. Please also make use of the comment sections to provide further details.

1. Patient Population

1.1 How big is the general population your clinic serves? _____ (Served population)

1.2 What is the incidence rate of geriatric patients (70 yrs or older) with hip fractures in your country/region? _____ (Geriatric patients with hip fractures per one million people per year)

1.3 How many patients (70 yrs or older) per year with hip fractures are treated in your clinic? _____ (per year)

1.4 Please read the inclusion and exclusion criteria for the planned clinical investigation below:

Inclusion criteria

a) Age 70 years or older
b) Geriatric patients with hip fractures
Treated either with Osteosynthesis or Endoprosthesis
c) Ability of the patient or assigned representative to understand the content of the patient information / Informed Consent Form
d) Signed and dated IRB/EC-approved written informed consent

Exclusion criteria

a) Any not medically managed severe systemic disease
b) Recent history of substance abuse (ie, recreational drugs, alcohol) that would preclude reliable assessment
c) Prisoner
d) Participation in any other medical device or medicinal product study within the previous month that could influence the results of the present study

1.5 Based on these criteria, how many patients per year could potentially be included in this clinical investigation at your clinic? _____ (per year)

2. Clinical Investigation Plan (CIP) specific questions

2.1 Are the following follow-up visits standard of care at your clinic?

12 weeks postsugery

☐ Yes
☐ No

1 year postsurgery

☐ Yes
☐ No

2.1.1 If any of the above listed follow-up visits are not standard of care at your clinic: Can these visits still be performed as follow-up visits?

☐ Yes
☐ No

2.1.2 Please provide an explanation, how you plan to participate in the clinical investigation. _____

2.1.3 Please elaborate if there would be any financial compensation required besides the regular investigator fee provided. _____

2.2 Is the documentation of any adverse event in the patient chart, whether or not they are related to the hip fracture, standard of care at your clinic?
- ☐ Yes
- ☐ No

2.2.1 If the documentation of any adverse events are not standard of care/available at your clinic: Can these procedures still be performed/provided?
- ☐ Yes
- ☐ No

2.2.2 Please provide an explanation, how you plan to participate in the clinical investigation. _____

2.2.3 Please elaborate if there would be any financial compensation required besides the regular investigator fee provided. _____

3. Organization of the orthopaedic patient managment

3.1 Is there a geriatrician available at your hospital?
- ☐ Yes; ortho-geriatrician
- ☐ Yes; general geriatrician
- ☐ No geriatrician

3.1.1 Title, name of the (responsible) geriatrician _____

3.1.2 Phone _____

3.1.3 Mobile _____

3.1.4 Email _____

3.1.5 Does the geriatrician see the patient at your hospital within 1 hour after admission?
- ☐ Yes
- ☐ No

3.1.6 Is there a daily round by the geriatrician starting from the first postoperative day until discharge?
- ☐ Yes
- ☐ No

3.2 Does the orthopaedic surgeon see the patient at your hospital within 1 hour after admission?
- ☐ Yes
- ☐ No

3.3 Is there a daily round by the orthopaedic surgeon starting from the first postoperative day until discharge?
- ☐ Yes
- ☐ No

3.4.1 Are there local medical guidelines for orthogeriatric patients, which have been consented by the orthopedic surgeons, geriatrician and anesthetist?
- ☐ Yes
- ☐ No

3.4.2 Are there local medical guidelines for orthogeriatric patients, which have been consented by the orthopedic surgeons and anesthetist?
- ☐ Yes
- ☐ No

3.5 Does a pre-defined patient pathway exist to guarantee a fast track in the emergency room?
- ☐ Yes
- ☐ No

3.6 Is a pre-defined order set for assessing laboratory values in place?
- ☐ Yes
- ☐ No

3.7 Does the patient receive physiotherapy every day during the postoperative phase?
☐ Yes
☐ No

3.8 Does the patient receive occupational therapy every day during the postoperative phase?
☐ Yes
☐ No

3.9 Does the patient have access to social workers, if required?
☐ Yes
☐ No

3.10 Is there a well-defined involvement of the staff nurses in the patient treatment process?
☐ Yes
☐ No

3.11 Does a daily communication among involved specialists take place?
☐ Yes
☐ No

3.12 Are there any special adaptations in the infrastructure to specifically improve the care of geriatric patients at your hospital?
☐ Yes
☐ No

3.12.1 If yes, please specify _____

3.13 Are there any other specifications which specifically improve the care of geriatric patients at your hospital?
☐ Yes
☐ No

3.13.1 If yes, please specify _____

4. Study site organization/accommodation of monitoring and project management/review board and ethics committee

4.1 How many externally sponsored (i.e not sponsored by internal funding at your clinic) clinical investigations in the field of hip fractures have been performed at your clinic in the past five years?
_____
(Clinical investigations in the past five years)

4.2 Are currently any other clinical investigations in the field of hip fractures being performed or planned at your clinic? _____

4.2.1 If yes, please specify _____

4.3 To monitor and manage the clinical investigation, personnel of AOCID and/or the sponsor will perform (among others) the following activities Can you accommodate these activities?

4.3.1 Visit your clinic for a Site Initiation Visit (duration: 4 hours).
☐ Yes
☐ No

4.3.2 Visit your clinic for a Site Monitoring Visit (duration: 8 - 12 hours).
☐ Yes
☐ No

4.3.3 Visit your clinic for a Site Close-Out Visit (duration: 8 - 12 hours).
☐ Yes
☐ No

4.3.4 Contact your Study Coordinator on a regular basis to follow-up on the progress of the clinical investigation.
☐ Yes
☐ No

4.3.5 Access the patient hospital charts to perform data checks during the monitoring visits.
☐ Yes
☐ No

4.3.6 Requiring broad-band internet (wireless or wired, or through a clinic station) during monitoring visits.
☐ Yes
☐ No

4.3.7 Require translation support from your staff during monitoring visits.

☐ Yes
☐ No

4.4 Please provide contact details of your Ethics Committee/ Institutional Review Board in the comment section Please also comment if you need any other review/approval prior to starting a clinical investigation.

_____

4.5 Did you have any issues with previous submissions of clinical investigations?

☐ Yes
☐ No

4.6 What language(s) is/are required for the Patient Information Sheet at your clinic?

_____

4.7 Contractual agreement: Please describe the process of obtaining a contractual agreement to perform this clinical investigation at your clinic Please comment on the expectations on remuneration (with special emphasis on any overhead (e.g scientific vs commercial rates)).

_____

4.8 To discuss your application to participate in this clinical investigation, we will contact you by phone Please provide two options when it is possible to call you (reserve 30 minutes for this call).

4.8.1 Contact person to be called

_____

4.8.2 Phone

_____

4.8.3 Option 1 (Day and time/time zone)

_____

4.8.4 Option 2 (Day and time/time zone)

_____

4.9 Additional comments/information

_____

4.10 Questionnaire completed by

_____