I. CLINICAL RESEARCH REGISTRATION DATA SET

1. Registration Number (assigned by INA REGISTRY)

   This number will be assigned by INA REGISTRY after submission approved

2. Date of registry approval (assigned by INA REGISTRY)

   Date when research is officially registered (approved) by INA REGISTRY, will be assigned by INA REGISTRY after approval

3. Registration date

   Date of research submission

4a. Secondary identifiers

   Identifiers issued by agencies such as sponsor, funding bodies or collaborative research groups, or protocol number and other registry

   ○ No

   ◉ Yes

4b. Name of issuing authority (for example protocol number, other registries, etc)

4c. Secondary identifier number

5. Primary sponsor

   The individual, organization, group, or other legal entity which takes responsibility for initiating, managing, and/or financing a study.
   The Primary Sponsor is responsible for ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder.

6. Source(s) of monetary or material support

   Major source(s) of monetary or material support for the trial (e.g. funding agency, foundation, company, institution)

7a. Secondary sponsor

- ○ No
- ◉ Yes

7b. Name of secondary sponsor

Separate your answer with a comma (,) for more than one sponsors

8. Other partners

Other essential institution(s) involved in research, Separate your answer with a comma (,) for more than one partners

9a. Principal investigator

9b. Principal Investigator's address

9c. City

9d. Country

9e. Principal investigator's affiliation

9f. Principal Investigator's email address

9g.Principal investigator's cellular phone

This data will not be published

10a.Contact person name for public queries

10b.Address for public queries

10c.City

10d.Country

10e.ZIP

10f.Affiliation for public queries

10g.Email address for public queries

10h.Phone number for public queries

11a.Name of Contact for scientific queries

There must be clearly assigned responsibility for scientific leadership to a named Principal Investigator.
The PI may delegate responsibility for dealing with scientific enquiries to a scientific contact for the trial.
This scientific contact will be listed in addition to the PI

11b.Address for scientific queries

11c.City

11d.Country

11e.ZIP

11f.Affiliation of scientific queries contact

11g.Email address for scientific queries

11h.Phone number for scientific queries

12a.Scientific study title

Scientific title of the study as it appears in the protocol submitted for funding and ethical review, including trial acronym if available

12b.Acronym of scientific study title

Please write the acronym of your study title if available

12c.Public (popular study title)

Title intended for the lay public in easily understood language, write the scientific title here, if the public title is absent

12d.Acronym of public title

13a.Ethical Approval number

13b.Name of Ethics comittee

13c.Date of Ethic approval

13d.Contact details of Ethic Committee (phone, email, and office)

14.Material Transfer Agreement number(MTA)

- ○ Not applicable
- ○ MTA number
- ○ Waiting for approval

15.Number of Persetujuan Pelaksanaan Uji Klinik (PPUK)/Persetujuan Protokol Uji BE (PPUB)

- ○ Not applicable
- ○ PPUK/PPUB number

16a.Countries of recruitment

Separate your answer with a comma (,) for more than one countries

16b.Study sites in Indonesia

17a.Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer,medication error)

If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented

17b.Purpose of the study

- ○ Treatment
- ○ Prevention
- ○ Diagnostic
- ○ Supportive care
- ○ Screening
- ○ Health services research
- ○ Basic science
- ○ Other

18a.Study type

- ○ Observational
- ◉ Interventional

18a.1.Interventional Study category

- ○ Bioequivalence study
- ◉ Clinical trial
- ○ Interventional, other than clinical trial

18b.Study phase

- ○ Phase 0 (exploratory trials)
- ○ Phase 1
- ○ Phase 1-2
- ○ Phase 2

○ Phase 2-3

○ Phase 3

○ Phase 4

18c.Method of allocation

○ Not Applicable (single arm study)

○ Non-randomized allocation

◉ Randomized allocation

18d.Description of the allocation concealment mechanism and sequence generation

18e.Masking

○ No (open)

○ Yes (blinded), who is masked

18f.Study intervention (study arm)

For drugs use generic name; for other types of interventions provide abrief descriptive name.
For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a temporary basis
For non-drug intervention types, provide an intervention name with sufficient detail sothat it can be distinguished from other similar interventions
If the intervention consists of several separate treatments, list them all in one line separatedby commas (e.g. "low-fat diet, exercise")

18g.Control intervention (control arm)

The control intervention(s) is/are the interventions against which the study intervention is evaluated (e.g. placebo, no treatment, active control)
If an active control is used, be sure to enter in the name(s) of that intervention, or enter "placebo" or "no treatment" as applicable
For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc)

18h.Intervention assignment

○ Single arm

○ Parallel

○ Crossover

○ Factorial

○ Other

19a.Inclusion criteria

Do not use any number or bullet, please separate the criteria with a comma (,)

19b.Gender inclusion criteria

☐ Male

☐ Female

☐ Not specified

19c.Minimum age

19d.Maximum age

19e.Exclusion criteria

Do not use any number or bullet, please separate the criteria with a comma (,)

20a.Type of enrollment

○ Actual

○ Anticipated

20b.Date of first enrollment

Anticipated or actual date of enrolment of the first participant

21a.Targeted Sample size

-

21b.Number of enrolled participants

22a.Name of primary outcome

The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effects of the intervention(s)
Most trials should have only one primary outcome

22b.Metric/method of measurement

22c.Timepoint(s) of measurement

23a.1.Secondary outcome 1 (SO1)

- ○ No
- ◉ Yes

23a.1n.Name of secondary outcome 1 (SO1)

Secondary outcomes are outcomes which are of secondary interest or that are measured at timepoints of secondary interest

23b.1.Metric/method of measurement (SO1)

23c.1.Timepoint(s) of measurement (SO1)

23a.2.Secondary outcome 2 (SO2)

- ○ No
- ○ Yes

24.Recruitment status

Initial: participants are not yet being recruited or enrolled at any site
Recruiting: participants are currently being recruited and enrolled
Complete: participants are no longer being recruited or enrolled
Suspended: there is a temporary halt in recruitment and enrolment

- ○ Initial
- ○ Recruit
- ◉ Complete
- ○ Suspended

25.Date of study completion (last participant, last visit)

26a.Brief summary of study results

26b.Date of results summaries

26c.Participant flow

26d.Baseline characteristic

26e.Adverse events

An unfavorable change in the health of a participant, including abnormal laboratory findings, and all serious adverse events and deaths that happen during a clinical study or within a specific time period after the study has ended.
This change major may not be caused by the intervention being studied

26f.Outcome measures

A table of data for each primary and secondary outcome measure and their respective measurement of precision (e.g. a 95% confidence interval) by the arm (that is, the initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any

27a.Publication for submitted study

- ○ No plan for published
- ○ Pending
- ◉ Yes, Mention 1st publication date on 27b

27b.Date of the first journal publication of results

28.URL hyperlink(s) related to results and publications

29.URL link to protocol file(s) with version and date

Make a specific folder in the URL that accessible for the reviewer and complete it with the approved version of the study protocol, IRB/Ethical approval, and MTA approval (if applicable)

30a.IPD sharing statement (Statement regarding the intended sharing of deidentified individual clinical trial participant-level data (IPD))

- ○ No
- ◉ Yes
- ○ Undecided

30b.Plan for IPD sharing (what IPD will be shared, when, by what mechanism, with whom, and for what types of analyses)

31.Other important informations

Save

Total process time: **1** second(s)