

Online Supplementary Materials

Figure S1. Search terms for systematic review

Figure S2. Articles included in systematic review

Supplementary Materials

Figure S1. Search terms for systematic review

Database: Pubmed

Terms:

(In EN, Change field to insert before text (no space):

http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=

clinical trial, phase i [pt] or "phase i" [tw] or "phase 1" [tw] or "phase 1/2" [tw] or "phase i/ii" [tw]

AND

(normal [tw] or healthy [tw]) and (participant* or volunteer* [tw] or men [tw] or women [tw] or adult* [tw] or children [tw] or research subjects [mh])

OR

Vaccine* [tw] and (participant* [tw] or volunteer* [tw] or men [tw] or women [tw] or adult* [tw] or children [tw] or research subjects [mh])

AND

adverse effects [sh] or adverse [tw] or safety or risk [mh] or risk [tw] or risk assessment [mh]

Database: Embase

Terms:

Phase 1 clinical trial/de or "phase 1/2" or "phase i/ii"

AND

Normal human/de or volunteer/de or men or women or children

OR

Vaccine/exp AND ('volunteer'/exp OR 'normal human'/exp OR men OR women OR children)

AND

Risk/de or risk assessment/de or risk-benefit analysis/de or adverse drug reaction/exp or side effect/exp

Database: Cochrane Central Register of Controlled Trials

Terms:

"phase i" [tw] or "phase 1" [tw] or "phase i/ii" [tw] or "phase 1/2"[tw]

and

(normal [tw] or healthy[tw]) and (volunteer* [tw] or "research subjects")

and

adverse [tw] or risk [tw] or toxic* [tw] or "side effects" [tw]

Database: Scopus

Terms:

phase i" OR "phase 1" OR "phase i/ii" OR "phase 1/2"

AND

((vaccine* OR normal OR healthy) AND (volunteer* OR "research subjects" OR participant* OR men OR women OR children))

AND

(adverse OR risk OR toxic* OR "side effects" OR safety))

Database: PsycInfo

Terms:

phase i" OR "phase 1" OR "phase i/ii" OR "phase 1/2"

AND

vaccine* OR normal OR healthy

AND

volunteer* OR subject* OR participant*
AND
adverse OR risk OR toxic* OR "side effects" OR safety

Figure S2. Articles included in systematic review

1. Abbas R, Hug BA, Leister C, Gaaloul ME, Chalon S, Sonnichsen D. A phase I ascending single-dose study of the safety, tolerability, and pharmacokinetics of bosutinib (SKI-606) in healthy adult subjects. *Cancer Chemother Pharmacol.* 2011; 69(1):221–7.
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Risks of Phase I Research with Healthy Participants: A Systematic Review

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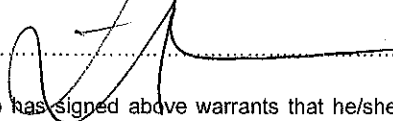
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