

# INPLASY

## Brain MRI-detected ischemic lesions as an endpoint in randomized clinical trials: a systematic review

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### ADMINISTRATIVE INFORMATION

**Support** - None.

**Review Stage at time of this submission** - Preliminary searches.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202510107

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 25 January 2025 and was last updated on 25 January 2025.

### INTRODUCTION

**Review question / Objective** Brain MRI-detected ischemic lesions (MRI-DILs) have been used as an endpoint in clinical studies of the treatment or prevention of ischemic stroke. MRI-DILs serve as a biomarker of brain injury, and, because MRI-DILs reflect both clinical and subclinical brain injury, they offer promise to serve as a surrogate endpoint for clinical stroke. Several randomized controlled trials have used MRI-DILs as either a primary or secondary endpoint.<sup>10,11</sup> Although some studies have found significant differences between study groups in terms of MRI-DILs, other studies have not. The fact that some clinical trials have not found differences in MRI-DILs between study groups has made the usefulness of MRI-DILs as an endpoint uncertain. We plan to perform a scoping review of the literature of all published randomized trials that have employed MRI-DILs as a primary or secondary endpoint. For each study, we will determine if there was a significant difference in

the volume or number of MRI-DILs between study groups. In analyzing these trials, we can better understand the utility of using MRI-DILs as an endpoint in future clinical studies.

**Rationale** This scoping review seeks to assess the overall feasibility and usefulness of using MRI-DILs as an endpoint in RCTs, and will also attempt to identify specific clinical research settings in which MRI-DILs, as an endpoint, hold the most promise.

**Condition being studied** Brain MRI-detected ischemic lesions.

### METHODS

#### Search strategy

Pubmed  
((magnetic resonance imaging) OR (MRI)) AND ((brain) OR (cerebral)) AND ((ischemic) OR (ischemia) OR (lesion)) AND ((randomized controlled trial) OR (randomised controlled trial)) AND ((number) OR (volume))

**Filters:**

- Years 1990-2024
- Human subject age 18
- English language publication

**Scopus**

((magnetic resonance imaging) OR (MRI)) AND ((brain) OR (cerebral)) AND ((ischemic) OR (ischemia) OR (lesion)) AND ((randomized controlled trial) OR (randomised controlled trial)) AND ((number) OR (volume))

**Filters:**

- Years 1990-2024
- Human subject age 18
- English language publication
- Medicine

**Cochrane CENTRAL**

((magnetic resonance imaging) OR (MRI)) AND ((brain) OR (cerebral)) AND ((ischemic) OR (ischemia) OR (lesion)) AND ((randomized controlled trial) OR (randomised controlled trial)) AND ((number) OR (volume)) in Title Abstract Keyword

**Filters:**

- Years 1990-2024
- English Language

**CINAHL**

((magnetic resonance imaging) OR (MRI)) AND ((brain) OR (cerebral)) AND ((ischemic) OR (ischemia) OR (lesion)) AND ((randomized controlled trial) OR (randomised controlled trial)) AND ((number) OR (volume))

**Filters:**

- Years 1990-2024
- Human
- Adults
- English language publication.

**Participant or population** Human subjects enrolled in randomized controlled trials using brain MRI-DILs as a primary or secondary endpoint.

**Intervention** N/A.

**Comparator** N/A.

**Study designs to be included** Randomized controlled trials using MRI-DILs as a primary or secondary endpoint.

**Eligibility criteria** English-language publications of adult human subject RCTs using MRI-DILs as an endpoint.

**Information sources** Pubmed, Scopus, Cochrane CENTRAL, and CINAHL.

**Main outcome(s)** Proportion of RCTs that have found a significant difference between study arms in terms of number and/or volume of brain MRI-DILs.

**Data management** N/A.

**Strategy of data synthesis** This is a descriptive study. We plan to summarize all published RCTs using MRI-DILs and identify possible disease states, interventions, or RCTs are more likely than others to find significant differences using MRI-DILs as an outcome measure.

**Subgroup analysis** N/A.

**Sensitivity analysis** N/A.

**Language restriction** English only.

**Country(ies) involved** United States.

**Keywords** magnetic resonance imaging, brain ischemic lesion, randomized controlled trial.

**Dissemination plans** We plan to submit the study manuscript to a peer-reviewed journal.

**Contributions of each author**

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