

Clinical trial registration:

This study was registered with ClinicalTrials.gov as follow:

1. NCT03108794

(<https://clinicaltrials.gov/ct2/show/NCT03108794?term=03108794&draw=2&rank=1>)

2. NCT01938820

(<https://clinicaltrials.gov/ct2/show/NCT01938820?term=01938820&draw=2&rank=1>)

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