Project Name

Statistical Report

26/04/2022

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**Trial registration number**:

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**Protocol version**: *Reference to version of protocol being used*

**Report revision**: *Report revision history*

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|  |  |  |

**Report contributors**:

*Names, affiliations, and roles of SAP contributors*

**Signatures**:

*Person writing the Report*

*Senior statistician responsible*

*Chief investigator/ clinical lead*

# Abstract

*A brief summary of the report and the conclusions. The aim is to make the reader understand what the report is about.Use ordinary, non-statistical language.*

# Introduction

*What is the problem and what is the structure of the report.*

# Objective of the report

*Short and precise description of the goal of the study/report.*

# Data

*What are the data and how were they obtained?*

# Methods

*Which methods have you used and why they were chosen.* *Reference to the SAP if available is sufficient. Additional analyses, not mentioned in the SAP, can be stated here.*

# Results

*Results of the analysis.*

## Screening data

## Baseline characteristics

## Main Outcome

## Secondary Outcomes

## Safety

# Conclusions

*Summary of what have been learned and what it means. Strength and limitations of the analysis.*

# References

*Include paper that are cited in the report*

# Tables

*If you do not want to include tables in the Results part directly.*

# Figures

*If you do not want to include figures in the Results part directly.*

# Supplemental Material

*Additional material*