Progress Report

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Title of Project
An evaluation of the impact of CGRP monoclonal antibodies on the cytokine profile of the immune system in migraine

Summary
Project synopsis
A cohort study of twenty patients with no symptoms, or history of inflammatory conditions or confounding medication who are commenced on a CGRP monoclonal antibody in treatment of chronic migraine (ICHD-3 criteria) was proposed.

Patients were recruited to participate in the Monash University Central Clinical School Neuroscience biobank, to allow storage and batching of clinical samples. Patients will have a total of 40ml of serum and plasma collected prior to commencement and following three months of therapy with a CGRP monoclonal antibody. Standard procedures for sample collection, handling and storage will be maintained, and patients screened for confounding intercurrent illness.

Following the period recruitment, samples will be analysed on a SIMOA HD-X Analyser, a sensitive digital immunoassay platform for measurement for fluid biomarkers. Quantification IFN-gamma-, IL-6, IL-10, IL-12p70, IL-17A, TNF-alpha will be undertaken, in order to determine if CGRP inhibition is associated with a shift in immune phenotype.

Progress to date:
In keeping with the projected timelines, twenty patients have been enrolled in the study, and following informed consent, donated 40ml of serum and plasma to the Neuroscience biobank prior to commencement of CGRP mAb, and following three months of therapy. The required assays to allow planned cytokine analysis were ordered following release of funds from the Brain Foundation in Quarter 1, 2023.

Unfortunately, due to a change in strategy and priorities by the vendor, they have informed the investigatory team that they will not fill the order in May 2023. As such, the team explored an alternate analysis with a vendor in the USA. The alternate analysis plan will include interferon gamma (IFNγ), IL-1β, IL-4, IL-5, IL-6, IL-8, IL-10, IL-12p70, IL-22, and Tumour Necrosis Factor alpha (TNFα). Currently, the samples have been transported and are being processed.

Projected timelines to completion:
Allowing time for analysis and write up, the study is expected to conclude in Quarter 1, 2024, with expected publication of results during Q2, 2024.

Hypothesis vs Findings
Not applicable pending analysis of results

Unanswered Questions
Not applicable pending analysis of results

What these research outcomes mean
Not applicable pending analysis of results