

## Children's Anti-inflammatory RELiever (CARE) study

### Rationale

One in seven children in NZ have asthma. This is one of the highest rates in the world. The impact on children is significant, with asthma accounting for 4.4 days off school, up to 10% of all NZ general practice (GP) consultations for children, and more than 3000 hospital admissions, every year.

Many children only use a short-acting reliever ("blue") inhaler ("puffer"), such as Ventolin or Respigen, which provides fast symptom relief, but does not treat swelling in the lungs that is often present; this can increase the risk of asthma attacks.

Two recent studies in adults found that Symbicort (an inhaler that combines a long-acting reliever and a weak steroid) taken only when needed was more effective than short-acting relievers at controlling asthma. In particular, Symbicort reduced asthma attacks by more than half. The 2020 NZ adolescent and adult asthma guidelines were changed in response to these findings, recommending that Symbicort be used instead of short-acting relievers.

There have been no similar studies in children; if comparable efficacy of this regimen is shown in childhood asthma, then its implementation would transform international guideline recommendations and has the potential to markedly reduce asthma morbidity globally.

### Study design

The CARE study has been designed by a team of international asthma experts and paediatricians. The aim of the study is to find out if there is a difference in the number of asthma attacks between the two treatments.

To do this, we plan to enrol 360 children across New Zealand. All children who take part will be randomly assigned to use Ventolin (a short-acting reliever) or Symbicort Rapihaler (a long-acting reliever with a weak steroid) for 1 year.

During the study, participants will attend five visits, at 13-weekly intervals. Three visits will be conducted either in person at a participating research site (Medical Research Institute of New Zealand (MRINZ) in Wellington Hospital, Lower Hutt After Hours Medical Centre, P3 Research Kāpiti, P3 Research Palmerston North (participant choice)) or virtually using video conferencing software and two via telephone. Visit procedures include completing asthma questionnaires and performing basic breathing tests (in person only).

The CARE study is sponsored by the MRINZ, and funded by the Health Research Council of New Zealand (20/389) and Cure Kids. It is approved by the Northern B Health and Disability Ethics Committee (20/NTB/200) and the Standing Committee on Therapeutic Trials (20/SCOTT/98).

### Benefits to participants

- Participants will receive regular asthma education, training, and contact from an experienced team of asthma researchers.
- Study inhalers are provided free of charge throughout the study.
- Participants enrolled into research studies tend to have better outcomes.
- Parent(s)/guardian(s) of participants will receive \$50 per in-person visit attended to cover the cost of transport.

### Benefits to Schools

- You will be assisting with world-leading research that could help to reduce the:
  - Asthma burden in children, including reducing time missed from school due to asthma.
  - Asthma burden on school staff, due to time spent managing poorly controlled asthma.