



Advantage Clinical
100 Advantage Way
Toronto Ontario
N1N 1N1

January 5th 2016

Dear Doctor Doe

Family Physicians Inc.
123 Clinical Site Lane

EARLY is a multi-centre, phase 3 study of AdvanRx (ACE Inhibitor) vs. placebo in patients with newly diagnosed, untreated hypertension.

Patients will be randomized in a 1:1 ratio to AdvanRx or placebo. Efficacy for all patients will be assessed BP assessments every 30 days for 90 days.

The primary efficacy endpoint is the mean reduction in systolic blood pressure in patients treated with AdvanRx. Primary safety endpoints are the adverse events, laboratory chemistry, vital signs, and ECGs.

EARLY is currently recruiting patients and more information about the study main criteria can be found in the following pages.

Please feel free to refer your patients or contact me for more information about this trial.

Sincerely,

Dr. Fiona Duncan
Advantage Clinical
100 Advantage Way
Toronto Ontario
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Your patients may be eligible for the EARLY if they have:

Inclusion Criteria:

1. Current diagnosis of hypertension defined as
 - a. Systolic Pressure >140mmhg and diastolic pressure >90mmg for twoconsecutive office visits OR
 - b. Ambulatory Blood Pressure Monitoring (24hour) mean systolic pressure of>140mmhg and mean diastolic pressure > 90mmhg
2. Age >18 years old

Exclusions include:

1. Received treatment with any of the following anti-hypertensive therapies
 - a. Thiazide Diuretics
 - b. Calcium channel blockers
 - c. ACE inhibitors
 - d. Angiotensin II receptor antagonists
 - e. Beta Blockers
2. Acute myocardial infarction (MI) in the past year
3. Body weight < 40kg
4. Currently enrolled in another investigational drug trial

Please contact our study coordinator, Jane Doe, at 555-555-5555 to refer patients you believe are eligible to be included to the EARLY study. We will be happy to provide additional information about the study.

Please do not hesitate to contact us if you need any further information.