

# **Importance of Randomized Controlled Trials (in Collaboration with Regional Partners): The meaning of EQUIPOISE**

**Buddha Basnyat, MD.**

**Chairman,**

**Oxford University Clinical Research-Unit, Nepal.**

# Randomized Controlled Trial

Randomized controlled trials (RCT) are **prospective studies** that measure the **effectiveness** of a new intervention or treatment.

Although no study is likely on its own to prove causality, randomization **reduces bias** and provides a **rigorous** tool to examine cause-effect relationships between an **intervention and outcome**.

## Backbone of Western Medicine

# EQUIPOISE

a state of genuine uncertainty on the relative value of 2 approaches being compared in a trial.

## Curiosity-driven

# RCTs

Efficacy and harm of pharmacological prevention of acute mountain sickness: quantitative systematic review.

Dumont L, Mardirosoff C, Tramèr MR.

BMJ. 2000 Jul 29;321(7256):267-72.

# RCTs

Efficacy of low-dose acetazolamide (125 mg BID) for the prophylaxis of acute mountain sickness: a prospective, double-blind, randomized, placebo-controlled trial.

**Basnyat B**, Gertsch JH, Johnson EW, Castro-Marin F, Inoue Y, Yeh C.

High Alt Med Biol. 2003 Spring;4(1):45-52. doi:  
10.1089/152702903321488979.

# RCTs

Acetazolamide 125 mg BD is not significantly different from 375 mg BD in the prevention of acute mountain sickness: the prophylactic acetazolamide dosage comparison for efficacy (PACE) trial.

**Basnyat B**, Gertsch JH, Holck PS, Johnson EW,

High Alt Med Biol. 2006 Spring;7(1):17-27.

# RCTs

Randomised, double blind, placebo controlled comparison of ginkgo biloba and acetazolamide for prevention of acute mountain sickness among Himalayan trekkers: the prevention of high altitude illness trial (PHAIT).

Gertsch JH, **Basnyat B**, Johnson EW, Onopa J, Holck PS.

BMJ. 2004 Apr 3;328(7443):797.

# RCTs

An open randomized comparison of gatifloxacin versus cefixime for the treatment of uncomplicated enteric fever.

Pandit A, Arjyal A, Day JN, et al

PLoS One 2007 Jun 27;2(6):e542



# RCTs

Gatifloxacin versus ceftriaxone for uncomplicated enteric fever in Nepal: an open-label, two-centre, randomised controlled trial.

Arjyal A, Basnyat B, Nhan HT et al

Lancet Infect Dis. 2016 May;16(5):535-545.

# RCTs

Phase 3 Efficacy Analysis of a Typhoid Conjugate Vaccine Trial in Nepal.

Shakya M, Colin-Jones R, Theiss-Nyland K et al.

N Engl J Med. 2019 Dec 5;381(23):2209-2218

# RCTs

Higher dose corticosteroids in patients admitted to hospital with COVID-19 who are hypoxic but not requiring ventilatory support (RECOVERY): a randomised, controlled, open-label, platform trial.

RECOVERY Collaborative Group

Lancet. 2023 May 6;401(10387):1499-1507.

## High Dose ( 20mg of dexamethasone) vs 6 mg

Country

Ghana	1 (<1%)	0
Indonesia	41 (6%)	31 (5%)
Nepal	317 (48%)	288 (47%)
South Africa	11 (2%)	3 (<1%)
Viet Nam	40 (6%)	28 (5%)
UK	249 (38%)	263 (43%)

# RCT

Azithromycin and cefixime combination versus azithromycin alone for the out-patient treatment of clinically suspected or confirmed uncomplicated typhoid fever in South Asia: a randomised controlled trial protocol.

Giri A, Karkey A, Dongol S et al

Wellcome Open Res. 2021 Nov 12;6:207

# EQUIPOISE

a state of genuine uncertainty on the relative value of 2 approaches being compared in a trial.

**Don't lose your equipoise.**

