

Clinical trials of polypill

TrialResults-center www.trialresultscenter.org

1 cardiovascular prevention

Trial	Treatments	Patients	Trials design and methods
polypill vs error			
TIPS , 2009 [NCT00443794] n=NA follow-up: 3 months	Polycap versus Polycap components in eight formulations	subjects aged 45 to 80 years of age with at least one additional cardiovascular risk factor	Parallel groups double-blind
GAP <i>ongoing</i> [ACTRN12608000583347] n=NA follow-up:	Polypill in 2 versions one tablet taken orally per day for an average of 18 months versus usual care	people at high risk of cardiovascular disease	Parallel groups open
IMPACT <i>ongoing</i> [ACTRN12606000067572] n=600 follow-up: 12 months	polypill once a day versus usual care	subjects at high risk of cardiovascular disease in primary care	Parallel groups open New Zealand
high dose polypill vs low dose polypill			
TIPS 2 <i>ongoing</i> n=500 follow-up:	Polycap containing twice the amounts of the constituents, which represent the doses of the individual drugs that are proven to reduce clinical events versus low-dose Polycap	-	
polypill vs placebo			
NCT00603590 <i>ongoing</i> [NCT00603590] n=475 follow-up:	fixed-dose combination therapy with two antihypertensive drugs, aspirin and atorvastatin versus placebo	men aged 50 to 80 (inclusive) and women aged 55 to 80 (inclusive) who are currently not eligible for or taking antihypertensive or lipid lowering therapy	Parallel groups double-blind iran
polypill vs usual care			
UMPIRE <i>ongoing</i> [NCT01057537] n=NA follow-up:	fixed-dose, once-daily combination polypill, the Red Heart Pill versus Usual cardiovascular medications	-	Parallel groups Open

continued...

Trial	Treatments	Patients	Trials design and methods
NCT00567307 <i>ongoing</i> [NCT00567307] n=200 follow-up:	Red Heart Pill 2b versus Usual Care	-	Parallel groups open Sri Lanka

More details and results :

- polypill for cardiovascular prevention in all type of patients at <http://www.trialresultscenter.org/go-Q418>

References

TIPS, 2009:

Yusuf S, Pais P, Afzal R, Xavier D, Teo K, Eikelboom J, Sigamani A, Mohan V, Gupta R, Thomas N Effects of a polypill (Polycap) on risk factors in middle-aged individuals without cardiovascular disease (TIPS): a phase II, double-blind, randomised trial. *Lancet* 2009 Apr 18;373:1341-51 [[19339045](#)] [10.1016/S0140-6736\(09\)60611-5](#)

Xavier D, Pais P, Sigamani A, Pogue J, Afzal R, Yusuf S The need to test the theories behind the Polypill: rationale behind the Indian Polycap Study. *Nat Clin Pract Cardiovasc Med* 2009;6:96-7 [[19104516](#)] [10.1038/ncpcardio1438](#)

GAP, :

ongoing trial [ACTRN12608000583347](#)

IMPACT, :

ongoing trial [ACTRN12606000067572](#)

TIPS 2, :

ongoing trial

NCT00603590, :

ongoing trial [NCT00603590](#)

Rastegarpanah M, Malekzadeh F, Thomas GN, Mohagheghi A, Cheng KK, Marshall T A new horizon in primary prevention of cardiovascular disease, can we prevent heart attack by "heart polypill"? *Arch Iran Med* 2008;11:306-13 [[18426322](#)] [08113/AIM.0012](#)

UMPIRE, :

ongoing trial [NCT01057537](#)

NCT00567307, :

ongoing trial [NCT00567307](#)