

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](#)