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КАЗАХСКИЙ НАЦИОНАЛЬНЫЙ  
МЕДИЦИНСКИЙ УНИВЕРСИТЕТ ИМЕНИ  
С.Д.АСФЕНДИЯРОВА

Проект тақырыбы: Влияние Losmapimod на сердечно-сосудистые  
исходы у больных, госпитализированных с острым инфарктом  
миокарда

Рандомизированное клиническое исследование

Орындаған: Махкамов М.

Тобы: Фа12-004-01

Тексерген: Джумагазиева О. Д..

Алматы - 2016

## Мәселе:

- ▶ Ауруханаға физикалық жүктеме нәтижесінде жүрек миокард инфаркты ауруына ұшраған 55 жастағы ер кісі алып келінді. Бұл науқасқа валидол препаратын тағайындады, ем бір апта жүргізілген соң науқаста өзгеріс күзетілмеді. Дәрігер қолданудағы препаратты Losmarimod препаратына ауыстырды. 10 күн дәріні қабылдаған соң науқастың жағдайы жақсара бастады.

Негізгі сұрақ:

Физикалық жүктеменің жүрекке әсері қандай ?

Қосымша сұрақ:

Валидолды Losartimod препаратына ауыстыру нәтижеліма ?

# РІСО бойынша:

- ▶ 1. Науқас 55 жастағы миокард инфарты ауруына ұшраған ер кісі
- ▶ 2. Валидол тағайындалды
- ▶ 3. Losartimod препаратына ауыстырылды
- ▶ 4. 10 күн дәріні қабылдаған соң науқастың жағдайы жақсара бастады.

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Effect of Losmapimod on Cardiovascular Outcomes in Patients Hospitalized With Acute Myocardial

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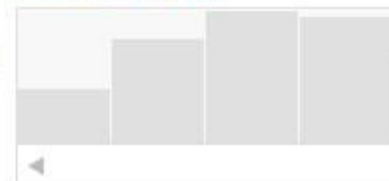
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## Losmapimod on Cardiovascular Outcomes in Patients Hospitalized With Acute Myocardial Infarction: A Randomized Clinical Trial.

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(352)

Background: Mitogen-activated protein kinase (MAPK)-stimulated inflammation is implicated in atherogenesis, plaque destabilization, and outcomes in myocardial infarction (MI). Pilot data in a phase 2 trial in non-ST elevation MI indicated that the p38 MAPK inhibitor losmapimod attenuates inflammation and may improve outcomes.

Objective: To evaluate the efficacy and safety of losmapimod on cardiovascular outcomes in patients hospitalized with an acute myocardial infarction.

**DESIGN, AND PATIENTS:** LATITUDE-TIMI 60, a randomized, placebo-controlled, double-blind, parallel-group trial conducted at 322 sites from June 3, 2014, until December 8, 2015. Part A consisted of a leading cohort (n = 3503) to provide an initial assessment of losmapimod's safety and efficacy before considering progression to part B (approximately 22,000 patients). Patients were considered potentially eligible if they had been hospitalized with an acute MI and had at least 1 additional predictor of cardiovascular risk.

Patients were randomized to either twice-daily losmapimod (7.5 mg; n = 1738) or matching placebo (n = 1765) on a background of guideline-recommended therapy. Patients were treated for 12 weeks and followed up for an additional 12 weeks.

**RESULTS AND MEASURES:** The primary end point was the composite of cardiovascular death, MI, or severe recurrent ischemia requiring revascularization with the principal analysis specified at week 12.

In part A, among the 3503 patients randomized (median age, 66 years; 1036 [29.6%] were women), 99.1% had complete adherence to treatment. The primary end point occurred by 12 weeks in 123 patients treated with placebo (7.0%) and 139 patients treated with losmapimod (8.1%; hazard ratio, 1.16; 95% CI, 0.91-1.47; P = .24). The on-treatment rates of serious adverse events were 16.0% with losmapimod and 14.2% with placebo.

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# Effect of Losmapimod on Cardiovascular Outcomes in Patients Hospitalized With Acute Myocardial Infarction: A Randomized Clinical Trial

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## ABSTRACT

ABSTRACT | INTRODUCTION | METHODS | RESULTS | DISCUSSION | CONCLUSIONS | ARTICLE INFORMATION | REFERENCES

**Importance** p38 Mitogen-activated protein kinase (MAPK)-stimulated inflammation is implicated in atherogenesis, plaque destabilization, and maladaptive processes in myocardial infarction (MI). Pilot data



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  - Рандомизированное клиническое исследование
- Effect of Losmapimod on Cardiovascular Outcomes in Patients Hospitalized With Acute Myocardial Infarction
  - A Randomized Clinical Trial



*Кілт сөздер: инфаркт мокарды және қатер*

*Keywords: myocardial infarction risk*

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*Postgraduate Medical School, Grochowski Hospital, Warsaw, Poland*

Цель. Оценить эффективность и безопасность losmapimod на сердечно-сосудистые исходы у пациентов , госпитализированных с острым инфарктом миокарда .

Objective. To evaluate the efficacy and safety of losmapimod on cardiovascular outcomes in patients hospitalized with an acute myocardial infarction.

Вмешательства. Пациенты были рандомизированы в два раза в день losmapimod ( 7,5 мг ; n = 1738 ) или плацебо ( n = 1765 ) на фоне основного положения рекомендованной терапии . Пациенты получали лечение в течение 12 недель и наблюдались в течение еще 12 недель

Interventions. Patients were randomized to either twice-daily losmapimod (7.5 mg; n = 1738) or matching placebo (n = 1765) on a background of guideline-recommended therapy. Patients were treated for 12 weeks and followed up for an additional 12 weeks.



Основные результаты и меры. Первичная конечная точка была составной сердечно-сосудистой смерти , инфаркта миокарда или тяжелой рецидивирующей ишемии , требующей неотложного коронарной реваскуляризации с основным анализом указанной в 12-й неделе

Main Outcomes and Measures. The primary end point was the composite of cardiovascular death, MI, or severe recurrent ischemia requiring urgent coronary revascularization with the principal analysis specified at week 12.

Результаты В части А, среди 3503 пациентов, рандомизированных (средний возраст 66 лет; 1036 [29,6%] были женщины), 99,1% имели полное выяснение для первичного результата. Первичная конечная точка произошла 12 недель у 123 пациентов, получавших плацебо (7,0%) и 139 пациентов, получавших losmapimod (8,1%; отношение рисков 1,16; 95% ДИ 0.91-1.47,  $p = .24$ ). Ставки по-лечения серьезных побочных эффектов были 16,0% с losmapimod и 14,2% в группе плацебо.

Results. In part A, among the 3503 patients randomized (median age, 66 years; 1036 [29.6%] were women), 99.1% had complete ascertainment for the primary outcome. The primary end point occurred by 12 weeks in 123 patients treated with placebo (7.0%) and 139 patients treated with losmapimod (8.1%; hazard ratio, 1.16; 95% CI, 0.91-1.47;  $P = .24$ ). The on-treatment rates of serious adverse events were 16.0% with losmapimod and 14.2% with placebo

- ▶ Выводы и актуальности Среди пациентов с острым инфарктом миокарда, применение losmapimod по сравнению с плацебо не снижает риск основных ишемических сердечно-сосудистых событий. Результаты данного поискового исследования эффективности не оправдывает перейти к более крупного исследования эффективности в существующей популяции пациентов.
- ▶ Conclusions and Relevance Among patients with acute MI, use of losmapimod compared with placebo did not reduce the risk of major ischemic cardiovascular events. The results of this exploratory efficacy study did not justify proceeding to a larger efficacy trial in the existing patient population.

## Пікір:

Losmarimod препараты протеинкиназаны стимулдеу нәтижесінде жүрек қабынуларын азайтады, соны нәтижесінде жүрек бұлшық еттерінде өзгерістер және қабыну процесстерін алдыны алады.