Introduction: Hypertension is a major risk factor for ischaemic and haemorrhagic stroke, myocardial infarction (MI), heart failure (HF), chronic kidney disease, cognitive decline and premature death. In 2008, approximately 40% of adults aged 25 years had been diagnosed with hypertension worldwide. According to the Italian Hypertension Society (SIAH), in Italy there are approximately 14 million of people who have elevated blood pressure (hypertension), but only 3 million receive appropriate therapy and just the 37% of those with controlled blood pressure. CVG is responsible for one-third of global deaths per year (approximately 17 million) and it is a leading and increasing contributor to the global disease burden. The high prevalence of hypertension worldwide has significantly contributed to the present pandemic of CVG.

Objectives: The objective of this study was to perform a Budget Impact Analysis (BIA) assessing the introduction of Trivram in the treatment of hypertension into the Italian market. Trivram is a single pill combination of statin (atorvastatin calcium trihydrate), calcium channel blocker (amlodipine besilate) and angiotensin-converting enzyme inhibitor (perindopril arginine) indicated for the treatment of essential hypertension and/or stable coronary artery disease.

Methods: The BIA compares two different scenarios: one without a triple fixed combination therapy (Scenario 1) vs. another one with the introduction of Trivram (Scenario 2). The study has been conducted considering the perspective of the Italian National Healthcare Service. Population data were obtained from a Local Project Database managed by Cegedim composed by 1.100,000 patients’ records originated from software used by 900 Italian GPs. The time horizon considered was 3 years from the introduction of Trivram. Total number of patients in each of the 3 years was the same for the two Scenarios, because the model allows only the switch of patients from the dual (Perindopril+Atorvastatin, Perindopril+Amlodipine, Amlodipine+Atorvastatin) or triple combinations (Perindopril+Amlopidine+Atorvastatin, Perindopril+Amlodipine+Atorvastatin) to the fixed dose treatment with Trivram. According to the Cegedim database, there are about 331 thousands patients treated with double or triple therapy (Table 1). The reference market for Trivram is composed by the patients that can switch from the double therapy because they do not reach target blood pressure (according to major clinical trials about 60% of the patients in double therapy with Atorvastatin and 50% of the patients in double therapy with Perindopril and Amlodipine) by all the patients currently in triple therapy (Table 1). The model assumed that the percentage of patients who switch to Trivram is 26%, 38% and 49% the first, second and third year respectively. The prices used in the model are ex-factory prices (Table 2) as published in AIFA web site after price cuts.

Results: The study shows that the introduction of Trivram leads to a reduction in the quantity of pills taken by patients [247,893,255, 270,691,934 and 287,356,690 in Scenario 1 and 224,916,946, 222,110,020 and 214,892,239 in Scenario 2, respectively in year 1, 2 and 3]. (Figure 1). With a cost of 12,90 €/month, the introduction of Trivram generates savings for the Italian NHS equal to 10,6, 22,4 and 33.5 €/months respectively in year 1, 2, 3 over the total expenditure of 91,114.8 and 126,14 €/millions related to the year 1, 2 and 3 in the first scenario. (Figure 2). As the majority of patients with hypertension require two or more agents to achieve their BP targets, simplifying treatment by reducing pill burden through the use of SPCs is one of the most straightforward and effective ways of improving adherence.

Conclusions: The present study indicates that the introduction of Trivram has two important effects:
1. It does not imply additional treatment costs, from the first year, actually, it generates a saving for the NHS.
2. The introduction of Trivram represents a benefit for the patients, especially for the elderly, because it improves the adherence to the therapy, thanks to the reduction in the number of pills taken. Better adherence is also linked to a reduction in the number of hospitalizations caused by therapy interruption and, consequently, permits to avoid the related costs.