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New method to determine the effectiveness of enzyme targeted therapies

Background

About third of the adult population is suffering from cardiovascular disease, such as hypertension or heart failure. The primary chosen drug to treat these diseases is the angiotensin converting enzyme (ACE) inhibitors. They are really popular drugs, being prescribed to about 12% of the adult population. ACE inhibitory treatment reduced mortality (from heart failure or stroke) by 20-40% in various cardiovascular studies.
Based on the SOLVD trial, it was estimated that the cost of an ACE inhibitor treatment is 115 USD / QALY (quality of life adjusted life year). It means that 115 USD investment is necessary to gain a high quality life year for patients with left ventricular dysfunction. The same figure for hypertensive patients is 680 EUR / QALY. In summary, ACE inhibitory treatment is highly preferable for the population (improvement in high quality life years) with limited costs to the society.
Nonetheless, the fact is that less than 50% of the population with ACE inhibitor prescribed takes the drugs properly. Clearly, a diagnostic technique to directly measure drug efficacy is missing to optimize ACE inhibitory treatment.

Technology

The present invention relates to methods for the fast (results usually obtained within minutes) measurement of the effectiveness of ACE inhibition in blood samples. The result is the level of inhibition (in %) in a single blood sample (serum or citrate plasma). The result is independent of the genotype or expression level of the ACE. According to the inventor's claim, ACE inhibitory medication is optimal in the range of 90-98%. Using this method, the ACE inhibitory treatment of the patients can be optimized: patients with lower than 90% inhibition may need increasing doses. The method can be applied to most of the used automated clinical chemistry analyzers.

Benefits

- The result is easy to interpret (% of inhibition);
- Simple sample handling;
- The method is selective for ACE inhibitors, but insensitive to the exact molecule;
- Cheaper than determination of the drug levels;
- Can be done in 30 min (much faster than the alternative methods).

Next stage of development

- A single center prospective clinical study involving 500 patients provided a proof of concept: more than 90% ACE inhibition is required (sufficient) for the optimal treatment of hypertension.
- The next step is a prospective multicenter randomized clinical trial to provide sufficient evidence for diagnostic guidelines to incorporate the method.

Who we are looking for

Stakeholders in clinical translation of the method: partners interested in personalized medicine and diagnostics to introduce the method to the market (finance and coordinate the randomized evidence test). Health service providers to establish a novel, objective measure for treatment efficacy and optimization of medical treatment.

IP status

Granted European and Hungarian patent.

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