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Vitamin B12 the key to oral insulin?

By Anna Lewcock

23/10/2007 - **Pfizer may have given up on its non-injectable insulin, but researchers in the US think they may have cracked a way to deliver the hormone orally, linking it up to vitamin B12 to protect it through the digestive system.**

Scientists at [Syracuse University](#) in New York believe they may have succeeded in conquering the main obstacles hindering the oral delivery of [insulin](#), managing to bypass the enzymatic digestion in the gut and overcoming poor enteric uptake.

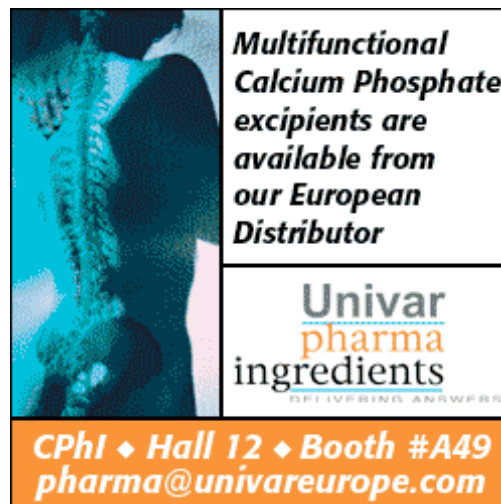
The solution has come in the form of [vitamin B12](#), a well-known vitamin B complex that helps in the synthesis of red blood cells and maintenance of the nervous system. Mammals have an active transport mechanism in the gastrointestinal tract for the absorption of the relatively large B12 molecule, a system that the researchers exploited in their attempts to develop an oral insulin solution.

The team believes that conjugating insulin to B12 molecules may protect bound proteins from digestion (with B12 uptake proteins acting as a protective carrier), as well as facilitating their transport into blood serum, thus trumping the two major hurdles to oral insulin delivery.

While delivery of insulin by inhalation has garnered much headline space (particularly in terms of the [latest Pfizer](#) revelations), this particular route of administration is likely to only be suitable for delivery of short-acting insulin analogues, say the report authors, and as such will be most effective in combination with a basal/bolus insulin therapy.

Developing a non-invasive method of insulin administration is a prime target for drug developers, attracted by the significant (and growing) diabetic patient population and the almost guaranteed interest a non-needle-based insulin solution would win from diabetics.

The Syracuse team's research showed that when its orally administered B12-conjugated insulin was tested in diabetic rat models, results demonstrated a significant decrease in blood glucose levels compared to the administration of



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free insulin.

Not only this, but the team's work also revealed that the glucose-lowering effects were clearly mediated by the B12 uptake mechanism.

However, while the results look very promising, the researchers point out that the human body's capacity for vitamin B12 uptake is limited to around 1-2ug per dose, and as such the amount of peptide that can be introduced through the B12 pathway could be limited.

This could be solved fairly easily, however, either by multiple dosing or by conjugating multiple insulin molecules to B12 (the research has so far only looked at one insulin peptide carried by one B12).

The research team, from the departments of chemistry and exercise science at Syracuse University, believe their research presents a viable oral insulin delivery mechanism with proven *in vivo* efficacy, which is also highly adaptive in terms of chemistry.

As to how an oral insulin option based on vitamin B12 might eventually appear on the market, researcher Robert Doyle told in-PharmaTechnologist.com that it could be as little as five years until the insulin pill could be available to patients.

While a tablet form of insulin is likely to appeal to [diabetes](#) sufferers currently having to inject themselves several times a day, the oral option is likely to be a little more costly than injectable insulin according to Doyle.

"Synthesis and purification are relatively straightforward," Doyle said.

"B12 is not inhibitive expensive so would compare favourably with inhaled or nasal insulin, for example, but more expensive than injectable insulin."

While there are [other firms](#) developing oral insulin products, the big players such as Novo Nordisk, Eli Lilly and up until last week Pfizer, seem to be more interested in the potential of the inhaled insulin market for the time being.

However, judging by some of the issues brought up by Pfizer's pulmonary insulin exploits, the oral route may prove a more attractive research direction for some firms hoping to avoid being stung in quite the same spectacular fashion as Pfizer.

Doyle said that the team is now looking for industry backing for its oral insulin project so as to be able to pursue the research *"in a more timely manner."*

"This project has produced a lead compound that opens the door for us to investigate new possibilities," he said.

"We are excited but cautious, and look forward to seeing where the research takes us."

The team's research has been published in the journal [ChemMedChem](#) and is available online.

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