New treatments

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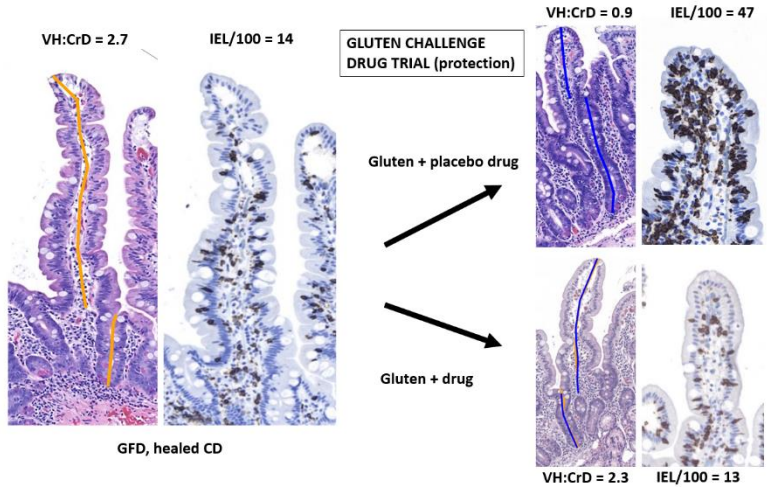
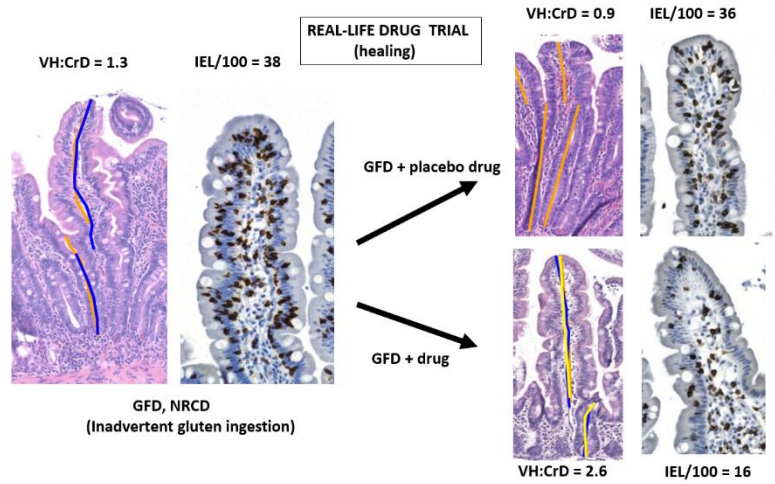


There is an unmet need for novel treatments, i.e. drugs, vaccines or medical devices, in patients suffering from gluten-induced disease entities/celiac disease, adjunct to a gluten-free diet or even replacing it. We designed a gluten challenge clinical drug trial for proof-of-concept phase 2a purposes and run the trials in Finland, first for ChemoCentryx, USA, testing the CCR9 antagonist CCX282-B, then copied the same design to test the glutenase enzyme ALV-003 for Alvine Therapeutics, USA, where the last trial was published (1), next came the anti-IL15 inhibitor trial AMG714 for Celimmune/Amgen, USA (2) and further we tested the transglutaminase 2 inhibitor ZED1227 for Dr. Falk Pharma, Germany, by using our design (3). With our Finnish collaborators we also run the gluten sequester BL-7010 phase 1-2 studies (BioLineRX, Israel).

Ongoing drug trials aim at therapies adjunctive to a gluten-free diet (real-life drug trials). We use standard operating procedures for small-intestinal biopsy processing and reading and we have validated the morphometric analysis readouts in celiac disease, separately for morphology and inflammation (4). Internationally centralized biopsy processing and quantitative digital histomorphometry reading is performed at prof. Jorma Isola lab (Jilab Oy Inc.) jilab.fi in Tampere (ISO 9001:2015) (5,6). Together with Dr. Keijo Viiri group Intestinal Signalling and Epigenetics (ISE) | Tampere Universities (tuni.fi) we are developing new molecular histomorphometry tools for clinical trial purposes and aim to reveal molecular mechanisms underpinning the efficacy of investigational medical products in celiac disease (7,8). We collaborate with international groups working on novel treatments for celiac disease (9,10).



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