

Colonoscopy Preparation

Biotech & Pharma

- A Novel Bowel Cleansing Product



Excellent prep	Good prep	Fair prep	Poor prep
>90% of mucosa seen, mostly liquid stool, minimal suctioning needed for adequate visualization ¹	>90% of mucosa seen, mostly liquid stool, significant suctioning needed for adequate visualization ¹	>90% of mucosa seen, mixture of liquid and semi-solid stool, which could be suctioned and/or washed ¹	<90% of mucosa seen, mixture of semi-solid and solid stool, which could not be suctioned and/or washed ¹

The goal of a good to excellent prep is, with the existing products, achieved in about 75% of the cases.

Picture from <http://www.maringastro.com/preparation-websites/>



The pudding! The patient eats it while drinking cold water. novel product looks and feels like a (good

Quote (and picture above left) from <http://health.sunnybrook.ca/navigator/colonoscopy-preparation-options/>:

QUESTION: I will soon be having a colonoscopy. I had one ten years ago. My doctor recommended the test to check for colon cancer. Now he says it's time to do it again. I didn't mind the procedure. But I hated drinking that horrible fluid beforehand to clean out my bowel. Why does that stuff taste so awful and is there an alternative?

ANSWER: Been there. Done that. And I know your pain.

Almost everyone who has had a colonoscopy – myself included – complains about the preparation.

The colonoscopy itself – in which a viewing scope is inserted in the rectum – isn't all that bad. Most patients are sedated when that's happening.

But there is no avoiding the dreaded prep. The colon needs to be as clean as a whistle before the doctor can insert the 5-to-6-foot long flexible scope into the colon.

So you will need to purge your intestines. The standard preparation is sold under several different brand names including PEGLYTE, GoLYTELY, COLYTE and KLEAN-Prep.

The kits usually consist of a container with a powdered mixture, to which you add four litres of water to form the solution. You then drink the concoction over a period of several hours on the day before your colonoscopy.

"The idea behind the preparation is that the large volume of fluid essentially washes out and cleanses the colon," explains Dr. Michael Bernstein, a gastroenterologist at Sunnybrook Health Sciences Centre.

"It is not a pleasant experience," acknowledges Annie Hui, a Sunnybrook pharmacist. "You will need to be at home where you have ready access to a bathroom. You are going to have watery bowel movements for hours – by the end of the prep, the rectal discharge will be clear fluid. Everything has been flushed out."

Indeed, it's a like a great whoosh going through your gastrointestinal passageway.

Drinking four litres of fluid would be a challenge by itself. However, it's the powdered mixture that provides the added burden of the awful taste.

One of the substances in the mixture is polyethylene glycol, which is sometimes used in small doses to treat constipation. It works by drawing water into the colon, which softens the stool and stimulates the movement of the muscles lining the colon, producing bowel movements.

The vile taste arises from the second key component of the mixture – electrolytes such as sodium and potassium, which are minerals that normally circulate in the blood and help regulate everything from nerve conduction to heart function.

Value proposition

Both European and North American guidelines advocate (read: you better) the use of "Split Dose" regimen.

Quote: Overall, 1 in 7 patients do not comply with a split-dose bowel regimen. Ensuring compliance with the split-dose bowel regimen will reduce the risk of a suboptimal bowel preparation. (*Gastrointest Endosc* 2014;79:811-20.)

Making it easier for the patients will improve the outcome with significant savings for the system, the formulation is likely to be patentable and thus ensuring exclusivity .

Commercial Perspectives

The team behind the invention is working towards a spin-out company, the institutions will offer the company an exclusive license to the novel formulation. The spin-out company is looking for potential investors and/or partners that can support them in bringing the product on the market.

The strategy is to introduce the product to a limited market (Denmark? Scandinavia?) and sell the success to a global player. A good candidate has been found and the negotiation awaits the results of the

Technology Summary

Using the collective insight, knowledge and wisdom of the team, a formulation which retains the key, recommended, ingredients of the existing product but that rather than representing a burden is actually palatable. (it looks, smells, tastes and looks like caramel-pudding The changes are expected, if anything, to reduce the main side effects associated with the existing products such as nausea and bloatedness (we can do little as to the resulting "diarrhea").

Development Phase

The formulation has successfully been tested in a small pilot trial. Production for the trial went smoothly but stability is as yet untested.

Based on those results, further improvements are being implemented and tested and added to the patent text.

A further pilot trial and large clinical trial are planned 2018.

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Technology Seeking: Funding/Investors/Licensee Partner

A patent application has been filed: PA 2016 70326 priority 18. May 2016

