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ESKİŞEHİR OSMANGAZİ ÜNİVERSİTESİ
KLİNİK ARAŞTIRMALAR ETİK KURULU
(LOCAL ETHIC BOARD-STUDY PROTOCOL)**

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TITLE: Superior Rectal Artery Embolization With Tri-acryl Gelatin Particles for Treatment of Symptomatic Hemorrhoids: Safety and Efficacy

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Study design: Double arm, parallel, single blinded, blocked randomized ,prospective study

Unique Protocol ID: 80558721/237

INTRODUCTION

Symptomatic hemorrhoidal disease is a still important public health problem although there are many surgical and nonsurgical minimal invasive treatment methods. Treatment methods are not satisfactory or invasive in some percent of the patients. Superior rectal artery embolization (SRAE) for hemorrhoids is an adapted technique derived from Doppler-guided hemorrhoidal artery ligation (DGHAL). In this technique, the distal branches of the superior rectal artery arising from the inferior mesenteric artery is occluded endovascularly with coils. Its feasibility and safety were supported by articles. Collateralization and recurrence was seen following coil embolization.

13 Nisan 2013 tarih ve 28617 sayılı Resmi Gazetede yayınlanan İlaç Ve Biyolojik Ürünlerin Klinik Araştırmaları Hakkında Yönetmelik:

(*) y) **Sorumlu araştırmacı:** Araştırma konusu ile ilgili dalda uzmanlık veya doktora eğitimini tamamlamış olup, araştırmaların yürütülmesinden sorumlu olan hekim veya diş hekimini,

(**) cc) (Ek:RG-25/6/2014-29041) **Koordinatör:** Çok merkezli bir araştırmada bu merkezlerin sorumlu araştırmacıları ile etik kurul, destekleyici veya destekleyicinin yasal temsilcisi ve gerekirse bunlar ile Kurum arasındaki koordinasyonun sağlanmasından sorumlu, uzmanlığını veya doktorasını tamamlamış hekim veya diş hekimini,

The purpose of this study is to compare safety and efficacy of 500-700 and 700-900 micron microspheric particles in superior rectal artery embolization.

MATERIALS AND METHODS

This is a double arm, parallel, single blinded, blocked randomized , prospective study. In each arm there will be 25 patients (any sex, between 18-75 years old). Local ethic board approved the study. Written informed consent will be obtained from the patients included in the study. Study will be conducted between December 2018 and December 2019.

Inclusion criteria as follows:

- Patients with symptoms of hemorrhoidal disease
- Patients with written informed consent
- Patients refusing surgery or other interventional methods
- Patients with high risk for surgery
- Patients accepting follow ups

Exclusion criteria as follows:

- Previous intervention
- Colorectal diseases other than hemorrhoids
- Patients with anal stenosis
- Patients with rectal prolapsus
- pregnant patients
- Patients with contraindications for technical steps or contrast usage.
- Patients do nor or could not give written informed consent

In experimental arms interventional embolization with 500-700 and 700-900 micron particles will be performed with 1 ml vials. Embolization procedure will be continued with vials until the stasis in SRAE will be achieved. Procedure will be performed only one time.

Primary Outcome Measures are as follow:

- Incidence of procedure related mortality (safety) [Time Frame: 12 month]. The mortality rate among the patients during 12 months related with interventional procedure.
- Incidence of procedure related complications (safety) [Time Frame: 12 month]. The morbidity rate among the patients during 12 months related with interventional procedure.
- Incidence of the patients' being free of symptoms from hemorrhoidal disease (efficacy) [Time Frame: 12 month]. The efficacy and clinical success of the procedure will be evaluated.

[Metni yazın]

Secondary Outcome Measures:

-Technical success [Time Frame: On the day of intervention]. The rate of interventions that were performed successfully.

- Recurrence [Time Frame: 3-6-12. months]. Recanalization or collateralization of the previously embolized rectal arteries.

Goligher's classification scale (prolapse stage), Bleeding severity score (French), Quality of life score, Visual analog scale score for pain will be used for follow ups.

Appropriate statistical analysis of primary and secondary outcomes will be used to describe the results of data obtained.

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