

Chinese Version of Experiment Ethic Approve Form:

杭州口腔医院医学伦理审查申请表

课题名称	显微根管手术后肿胀发生情况调查及危险因素研究		
研究类型	1. 观察性研究: <input checked="" type="checkbox"/> 病例对照 <input type="checkbox"/> 队列研究 2. 实验研究: <input type="checkbox"/> 临床实验 <input type="checkbox"/> 社区干预 3. 其他:		
预计研究周期	1 年	主要研究者	毕成
申请科室	显微牙科中心	联系人	毕成
联系电话		电子邮箱	20161040@zcmu.edu.cn
<p>报送材料清单:</p> <p>1. 申请项目的临床前整套研究资料摘要 (✓)</p> <p>2. 临床研究方案 (✓)</p> <p>3. 临床研究方案摘要包括研究流程图 (✓)</p> <p>4. 研究者手册 ( )</p> <p>5. 研究病历、病历报告表 (✓)</p> <p>6. 向受试者提供的知情同意书 (✓)</p> <p>7. 用于招募受试者的资料 (包括布告、广告、影视材料等) ( )</p> <p>8. 主要研究者的最新专业履历 (✓)</p> <p>9. 主要研究者的委托书 ( )</p>			
<p>研究者申请理由:</p> <p>显微根管手术后组织肿胀是术后常见的并发症之一,过度的肿胀可能会对患者的工作和生活产生一定的困扰。通过探究显微根管手术后引起肿胀的潜在危险因素,并构建相关模型,能够在临床上给予外科手术医师在术后的给药以及病人的组织肿胀情况上一定的指导作用,有一定程度上的参考价值。</p> <p style="text-align: right;">负责人签字 <i>汪海峰</i> 2021年6月9日</p>			
<p>科室审查意见</p> <p style="text-align: right;">科主任签字 <i>毕成</i> 2021年6月9日</p>			
<p>伦理委员会审核意见:</p> <p>经审查,“显微根管手术后肿胀发生情况调查及危险因素研究”项目,将在征得受试者知情同意后,经医院伦理委员会审核,此项符合卫生部相关规定,同意并开展研究。</p> <p style="text-align: right;">杭州口腔医院医学伦理委员会 2021年6月9日</p>			

English Translation of Experiment Ethic Approve Form:

## Hangzhou Dental Hospital Medical Ethics Review Application Form

Subject Name	Incidence and Risk Factor analysis for Swelling after Apical Microsurgery		
Type of Research	1. Observational studies: <input checked="" type="checkbox"/> case-control, <input checked="" type="checkbox"/> cohort studies 2. Experimental studies: <input checked="" type="checkbox"/> clinical trials, <input checked="" type="checkbox"/> community interventions 3. Other		
Expected research period	1 year	Principal Investigator	Cheng Bi
Application Section	Micro dentistry Center	Contact person	Cheng Bi
Contact number		Email	20161040@zcmu.edu.cn
<p>List of materials to be submitted:</p> <ol style="list-style-type: none"> <li>Summary of the preclinical research package of the applied project( ✓ )</li> <li>Clinical study protocol( ✓ )</li> <li>Summary of the clinical study protocol including the study flow chart( ✓ )</li> <li>Investigator's manual ( )</li> <li>Study medical record and medical record report form( ✓ )</li> <li>Informed consent provided to subjects( ✓ )</li> <li>Information used to recruit subjects (including bulletins, advertisements, film and television materials, etc.) ( )</li> <li>Updated professional biographies of the principal investigators( ✓ )</li> <li>Power of attorney for the principal investigator ( )</li> </ol>			
<p>Reason for investigator application:</p> <p>Tissue swelling after micro-apical surgery is one of the common postoperative complications, and excessive swelling may cause some disturbance to patients' work and life. By investigating the potential risk factors for swelling after micro-apical surgery and constructing a relevant model, we can provide some clinical guidance to surgeons on the postoperative administration of medication and tissue swelling of patients.</p> <p style="text-align: right;">Person in charge: Shuhua Wang 2021.6.9</p>			

Section Review Comments:

Section Chief: Cheng Bi  
2021.6.9

Ethics Committee Review:

The project "Incidence and Risk Factor analysis for Swelling after Apical Microsurgery" was reviewed and will be conducted with the informed consent of the subjects. The ethics committee of the hospital has reviewed the project and found that it is in compliance with the relevant regulations of the Ministry of Health and agreed to conduct the study.

Medical Ethics Committee of Hangzhou Dental Hospital  
2021.6.9