

齐齐哈尔市第一医院
拟开展医疗新技术审批表

项目名称 经皮股骨头扩大减压治疗股骨头缺血性坏死

申报科室 骨外二科

项目负责人 张金柱 、林林

申报日期 2013-1-15

填 写 说 明

- 一、 申报表各项内容，必须实事求是，表达要明确、严谨，字迹要清晰易辨。
- 二、 本申请书一式 1 份，用 A4 纸打印，并于左侧装订成册。
- 三、 本申请书应附如下资料：
 - 1、 科室基本情况说明（包括床位数、人员编制、设备和技术条件情况等）
 - 2、 拟开展新技术的可行性论证报告
 - 3、 与本项目相关的管理制度和质量保障措施（技术规范、操作规程）
 - 4、 与本项目相关的《知情同意书》模板
 - 5、 相关的临床试验研究报告

新技术引进准入申请表

项目名称		经皮股骨头扩大减压治疗股骨头缺血性坏死					
科 别		骨外二科		拟开展时间		2013-2	
项目 组 主 要 成 员	姓 名	性 别	年 龄	职 称	专 业	分 工	
	张金柱	男	55	主任医师	骨外科	主持	
	林林	男	32	主治医师	骨外科	共同主持	
	罗先国	男	49	主任医师	骨外科	参与实施	
	王尔健	男	34	主治医师	骨外科	参与实施	
	张俊峰	男	35	主治医师	骨外科	参与实施	
	窦志	男	33	主治医师	骨外科	参与实施	
<p>技术简介（来源、国内外地位、社会效益、经济效益、医学伦理、法律法规）</p> <p>股骨头减压术是目前国内外一致认可的治疗 I、II 期股骨头缺血性坏死的首选方法。经皮股骨头扩大减压治疗股骨头缺血性坏死通过潜行扩大器的应用，在达到治疗效果的同时将损伤降到了最小程度。经全国多家知名医院临床使用多年，治疗效果反映良好。该治疗方法也可配合其他手术方法，如配合干细胞移植、进口钽棒等多项手术增强手术效果。该治疗方法操作简单、安全、快捷，大大减少手术创伤、缩短手术时间，降低患者痛苦和经济负担。经皮股骨头扩大减压治疗股骨头缺血性坏死技术日后定会被广泛应用与临床，为患者解决病痛、为医院带来良好的社会效益和经济效益。</p>							
<p>实现本项目预期目标已具备的条件（技术人员水平、设备资源情况、患者来源情况）：</p> <p>我科室拥有主任医师 4 人、副主任医师 1 人、主治医师 5 人、住院医师三人，技术力量强、科室医护人员配合默契，多次攻破医疗技术难关。</p> <p>我院中心手术室拥有两台 C 型臂 X 线机几张骨科手术床，我科室医生均能熟练掌握以上设备的使用。</p> <p>股骨头缺血坏死患者众多，自核磁共振广泛使用后早期股骨头缺血性坏死病例更多、更早的被发现。</p>							

适应症及禁忌症:

适应证: 1. II、III_{AB} 期, II 期坏死界限清楚。

2. 年龄 40 岁以下, 可扩展为 III_C 及 IV 期, 股骨头变形不重且保留关节间隙者。

3. 保留有较好的关节活动度 (屈髋大于 90°)。

禁忌证: 1. 股骨大转子部有感染灶。

2. 合并有类风湿关节炎、强直性脊柱炎及髋关节发育不良者。

3. III 期塌陷大于 4mm。

4. 坏死体积大于 50% 或虽小于 50% 但髋关节屈曲活动小于 90°。

与其他医疗技术治疗同种疾病的比较 (风险、疗效、费用、疗程等方面)

1. 单纯髓芯减压不能预防或纠正股骨头塌陷, 反而会加速股骨头的塌陷。

2. 传统的髓芯减压+带血管蒂骨瓣移植手术时间长、出血多、手术操作复杂, 且术后需较长时间的固定, 无法在术后早期进行功能练习, 不利于患者的康复。

经皮股骨头扩大减压治疗股骨头缺血性坏死通过潜行扩大器的应用, 在达到治疗效果的同时将损伤降到了最小程度。该治疗方法也可配合其他手术方法, 如配合干细胞移植、进口钽棒等多项手术增强手术效果。

风 险 评 估	可 预 见 风 险	1. 股骨头减压过度导致股骨头骨折、塌陷。 2. 股骨颈骨道骨折。 3. 其他术后卧床并发症。
	防 范 措 施	1. 术中精确定位、减压到位。 2. 术后定期来院复查, 遵医嘱患肢负重活动。 3. 积极、有效、细致的术后护理, 具体详细术后康复计划。

医务部意见:

通过。





Application Number: 1I01BX000671-01A2

Principal Investigator(s):
WEIKUAN GU, PHD

Project Title: Study of the Genetic Basis for Fibrotic Diseases in a Mouse Model

St. Arnold, Peter A.
Memphis VA Medical Center
1030 Jefferson Avenue
Memphis, TN 381042127

We are pleased to inform you that funding in the amount of \$275,187 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) is being considered to support the above named project at MEMPHIS VA MEDICAL CENTER.

This is not an indication, however, of the final award. For some ORD Research & Development Services, the budget in Section I reflects the recommendations of the review panel and other administrative changes; for other R&D Services, the budget reflects what was requested in the application.

Budget negotiations may occur as part of the JIT process. Because we may not yet have a fiscal year budget and all just-in-time (JIT) issues have not been resolved, project start dates are uncertain. We will attempt to maintain continuity for ongoing programs, but negotiation of start dates will not begin until all required JIT documentation has been approved. Please note that, as always, funding is dependent upon the availability of funds.

A final Notice of Award will be issued after all JIT issues have been resolved and all budget negotiations are completed. Refusal of this award must be communicated to the appropriate representative of the ORD Research & Development Service named above.

Each publication, press release or other document that cites results from VA-supported research must include an acknowledgment of VA support and disclaimer (e.g., "The project described was supported by Award Number I01BX007080 from the Biomedical Laboratory Research & Development Service of the VA Office of Research and Development").

If you have any questions about this award, please contact the individual(s) referenced in Section II below.

Additional information follows

SECTION I – PROPOSED AWARD DATA – 1I01BX000671-01A2**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$196,465
Personnel Costs (Subtotal)	\$196,465
Equipment	\$50,000
Travel Costs	\$1,000
Other Costs	\$27,722

TOTAL PROPOSED AWARD AMOUNT \$275,187

SUMMARY OF PROPOSED TOTALS FOR ALL YEARS	
YR	THIS AWARD
1	\$275,187
2	\$227,503
3	\$229,888
4	\$232,344

Recommended future year total cost support is subject to the availability of funds and satisfactory progress of the project

SECTION II – CONTACT INFORMATION – 1I01BX000671-01A2

The Scientific Review Officer (SRO) named below is responsible for the determination of the proposed budget shown in Section I above. This budget may reflect recommendations of the reviewers, as well as administrative changes needed to meet the requirements of the awarding ORD Research and Development Service. Initial inquiries about the proposed budget should be directed to:

SRO: Susan Antonia Stern

Email: susan.stern@va.gov **Phone:** (202) 443-5703 **Fax:** (202) 495-6156

SECTION III – TERMS AND CONDITIONS – 1I01BX000671-01A2

This award is based on the above titled application submitted to and approved by VA-ORD, and is subject to the terms and conditions incorporated either directly or by reference in the following:

- a. All awards are dependent upon the availability of funds.
- b. Funding is contingent upon the review and approval of JIT compliance documentation and resolution of any administrative issues. Remember that all information provided must be current and that documentation, including proposal title and principal investigator name, must correspond exactly to the work described in the application. Please complete JIT documentation as soon as possible.
- c. Award recipients are responsible to ensure that VA is properly acknowledged on all public reports and presentations. Failure to acknowledge VA affiliation and support may result in termination of the award. For additional information, please refer to http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=361.
- d. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

SECTION IV – BX Special Terms and Conditions – 1I01BX000671-01A2

Personnel Costs (Subtotal) in Section I above include Salary and Fringe Benefits for the PI and all other individuals named in the budget section of the application. If not listed separately, Fringe benefits are included in Salaries and Wages.

This award is subject to all budgetary constraints/limits described in the VA SF-424 Application Guide and the specific RFA to which this application was submitted.

All funded interventional clinical trials must be registered in ClinicalTrials.gov before funds can be released, and certification must be received from the Facility Director that appropriate resources will be provided for oversight.

Award recipients are responsible for reporting inventions derived in the performance of work under this project. For additional information, please refer to http://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=403.